Supreme Court, U.S.
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No. _____

In The

Supreme Court of the United States

October Term, 1995

LYNNBROOK FARMS,
an Illinois General Partnership,

Petitioner,

v.

SMITHKLINE BEECHAM CORPORATION,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Seventh Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Are traditional state law causes of action seeking remedies for harm to livestock and other animals caused by unsafe and inefficacious animal vaccines preempted by an Animal and Plant Health Inspection Service ("APHIS") express declaration of preemption of state requirements which are different from, or in addition to, those imposed by the United States Department of Agriculture ("USDA") regarding the safety, efficacy, potency or purity of animal biologic products which are regulated by the USDA pursuant to the Virus-Serum-Toxin Act, 21 U.S.C. §§ 151-159 (1913) (amended 1985) ("VSTA") and which have been licensed by APHIS, thus leaving injured plaintiffs without a remedy?

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PETITION FOR WRIT OF CERTIORARI

The Petitioner, Lynnbrook Farms, respectfully requests that a Writ of Certiorari issue to review the judgment and opinion of the United States Court of Appeals for the Seventh Circuit entered in the present case on March 21, 1996, which held that state law damages claims were preempted as such claims were state requirements which were different from, or in addition to, requirements imposed by the United States Department of Agriculture ("USDA") under the Virus-Serum-Toxin Act ("VSTA"), 21 U.S.C. §§ 151-159 (1913)(amended 1985). App. D, A-39. A Writ of Certiorari is necessary in order to review the validity of the Seventh Circuit's decision.

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Seventh Circuit that gives rise to this petition appears at Appendix A to this petition (App. A, A-1) and is reported at 79 F.3d 620 (CA7 1996). By order filed April 22, 1996, the Seventh Circuit denied the petition for rehearing and suggestion for rehearing en banc, which order appears at Appendix C to this petition. App. C, A-38.

The opinion of the United States District Court for the Central District of Illinois, Peoria Division, appears at Appendix B to this petition (App. B, A-23) and is reported at 887 F.Supp. 1100 (C.D.Ill. 1995).

JURISDICTION

The judgment of the United States Court of Appeals for the Seventh Circuit was entered on March 21, 1996. App. A, A-1. On April 22, 1996, the Seventh Circuit denied Lynnbrook Farm's timely-filed petition for rehearing and suggestion for rehearing en banc. App. C, A-38. Pursuant to Supreme Court Rule 13.1, this Petition for a Writ of Certiorari has been filed within 90 days after the date of entry of the Seventh Circuit's order denying the petition for rehearing.

The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Appendix D sets forth verbatim the following statutory and regulatory provisions: 21 U.S.C. §§ 151-159 (1913) (amended 1985)(App. D, A-39); 9 C.F.R. § 112.2(b) (1991) (excerpt)(App. D, A-49); 57 Fed. Reg. 38758 (August 27, 1992)(App. D, A-50); S. Rep. No. 99-145, 99th Cong., 1st Sess. at 338-9 (1985)(App. D, A-45).

STATEMENT OF THE CASE

In clear conflict with the fundamental legal principles established by this Court in *Medtronic, Inc. v. Lohr*, Nos. 95-754 & 95-886, 1996 WL 345805 (U.S. June 26, 1996), the United States Court of Appeals for the Seventh Circuit held that an express declaration of preemption of state requirements which are different from, or in addition to, United States Department of Agriculture ("USDA") requirements, as stated in a Final Rule issued by the USDA's Animal and Plant Health Inspection Service ("APHIS") in 1992, preempts traditional state law claims for remedies relating to injuries caused by defective animal vaccines which have been licensed by APHIS pursuant to the Virus-Serum-Toxin Act ("VSTA"). *See generally* App. A, A-1; App. D, A-39,50. This petition now asks this Court to review a question of profound significance to all livestock producers, veterinarians, animal vaccine manufacturers, individual states, and the general consuming public, i.e., whether manufacturers may be held liable under traditional state laws for harm caused by dangerous, worthless, contaminated, harmful, unsafe, inefficacious or otherwise defective animal vaccines and analogous products which have been licensed by APHIS.

A. Background of Federal Regulation of Animal Vaccines

In 1913, Congress passed the Virus-Serum-Toxin Act ("VSTA") for the purpose of assuring the public that biologic products used in the treatment of animals are pure, safe, potent and efficacious. App. D, A-53,45. To achieve that goal, VSTA made it unlawful for any person, firm or

corporation to prepare or sell "any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals" and to prepare or sell any animal biologic product "unless and until [the product] shall have been prepared, under and in compliance with regulations prescribed by the Secretary of Agriculture, at an establishment holding an unsuspended and unrevoked license". 21 U.S.C. § 151 (1913)(amended 1985); App. D, A-39.

Congress adopted the 1985 amendments to VSTA for the purpose of bringing "intrastate" vaccines (i.e., vaccines produced and sold within a single state) under USDA control. App. D, A-45-48. Prior to the 1985 amendments to VSTA, intrastate vaccines could completely escape USDA regulation, while only those vaccines moving in interstate commerce were under the USDA's jurisdiction. *Id.* However, since most states did not actively regulate intrastate animal biologic products, those intrastate products were "almost entirely free of any official scrutiny in...33 states." *Id.* Recognizing the truly national markets and interstate movement of animal products as well as the need to assure "livestock owners, veterinarians and the American public that there is an ample supply of safe and effective animal vaccines and other biological products", Congress discarded the artificial distinction between interstate and intrastate vaccines and brought all animal biologic products under federal control via a single, uniform licensing system. *Id.* Neither VSTA nor its legislative history, however, makes any reference to concerns over common law product liability actions or whether Congress considered such actions to be a burden on the animal vaccine industry or on interstate commerce. *Id.*

Section 154 of VSTA authorizes the Secretary of Agriculture to issue and revoke licenses and to make such rules and regulations as may be necessary to prevent the preparation or sale of any worthless, contaminated, dangerous, or harmful animal vaccines or analogous products. 21 U.S.C. § 154 (amended 1985); App. D, A-40.

In reaction to the 1985 VSTA amendments, APHIS issued a Final Rule in 1992 declaring that:

> "...States are not free to impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency or purity of a product."

See App. D, A-50,54.

B. Procedural Background Of The Present Case

The Petitioner, Lynnbrook Farms, filed this action in the United States District Court for the Central District of Illinois, Peoria Division, on May 18, 1994, seeking recovery against the Respondent, Smithkline Beecham Corporation, and its predecessor in interest, Norden Laboratories, upon traditional state law causes of action (i.e., strict liability, failure to warn, fraudulent misrepresentation and consumer fraud based on false advertising and promotion, and breach of implied warranties of merchantability and fitness). Lynnbrook Farms alleged that its cattle suffered injuries after they were vaccinated with USDA-licensed animal vaccines manufactured by Smithkline Beecham, namely *CattleMaster 4 and

Ultrabac 7/Somubac, and that those vaccines were inefficacious, unsafe, unreasonably dangerous, and defective.[1] The District Court had jurisdiction pursuant to 28 U.S.C. § 1332 based on diversity of citizenship with an amount in controversy in excess of $50,000. App. B, A-24.

On November 2, 1994, Respondent moved for summary judgment on all counts of Lynnbrook Farms' Amended Complaint claiming that Lynnbrook Farms' state law claims were preempted in their entirety by the aforesaid express declaration by APHIS. App. A, A-3. Implied preemption was not claimed by Smithkline Beecham. App. A, A-5 n.1. On March 30, 1995, the District Court, accepting as true the material allegations contained in Lynnbrook Farms' Amended Complaint, granted Smithkline Beecham's Motion for Summary Judgment and held that all of Lynnbrook Farms' state law claims were preempted by APHIS' declaration despite that the Court was "troubled by the absence of a federal remedy". App. B, A-24,37. On April 28, 1995, Lynnbrook Farms filed its Notice of Appeal.

On March 21, 1996, the United States Court of Appeals for the Seventh Circuit affirmed the decision of the District Court and held that APHIS' express declaration of preemption of state "requirements" encompassed all of

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[1] Lynnbrook Farms' complaint was filed against both Norden Laboratories and Smithkline Beecham, but suit continued only against Smithkline Beecham due to a merger on or about January 1, 1992 of Norden into Smithkline Beecham, Norden's successor in interest. *See* App. B, A-24.

Lynnbrook Farms' state law claims.

The Seventh Circuit based its decision that state "requirements" encompass state common law actions primarily on an analysis of the term "requirements" in this Court's opinion in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), as well as in circuit court cases involving the same preemption language in the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136v(b), and in the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a). The Seventh Circuit held that the language in these *statutes* was not distinguishable "in any meaningful way" from the language used in APHIS' *regulatory* declaration. App. A, A-14-17.

The Seventh Circuit, unlike the District Court below, did except from preemption, in dictum, any state law claims arising from non-compliance with USDA requirements. Simply because the vaccines involved in the present case were licensed by APHIS, however, the Seventh Circuit held that APHIS had declared these vaccines to be safe and efficacious and thus in compliance with its standards, thereby automatically precluding Lynnbrook Farms' state law claims. App. A, A-18. The Seventh Circuit, like the District Court, acknowledged that its conclusion would leave Lynnbrook Farms and similar consumers of licensed vaccines with "no remedy for the injuries and losses that they have suffered" resulting from such vaccines. App. A, A-21; App B, A-37.

On April 3, 1996, Lynnbrook Farms filed its petition for rehearing and suggestion for rehearing en banc which the Seventh Circuit then denied on April 22, 1996.

REASONS FOR GRANTING THE WRIT OF CERTIORARI

I.

The Seventh Circuit has Decided an Important Federal Question in a Way Which Conflicts With Relevant Decisions of This Court.

The Seventh Circuit based its finding of common-law preemption by APHIS primarily in the face of "strong and consistent authority" from numerous circuit courts interpreting the preemption language in the Medical Device Amendments ("MDA"). App. A, A-17. On June 26, 1996, however, this Court issued an Opinion relating to the MDA which establishes a clear conflict with the legal principles asserted by the Seventh Circuit in its judgment in the present case. *See Medtronic, Inc. v. Lohr*, Nos. 95-754 and 95-886, 1996 WL 345805 (U.S. June 26, 1996). Despite the statutory preemption language in the MDA, which is indistinguishable from APHIS's regulatory preemption declaration in this case, this Court, unlike the Seventh Circuit, allowed the plaintiffs' traditional state tort claims for remedies to survive. Granting of this petition is thus required by the clear conflict that exists between the Seventh Circuit's decision below and this Court's decision in *Medtronic*.

A. Conflict Regarding the Preemptive Scope of "State Requirements"

This Court's finding of no express preemption in the *Medtronic* case centered around the Congressional language

in the MDA which states as follows:

> "...no state or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

Medtronic, slip op., at 8-9 (opinion of Stevens, J.)(citing 21 U.S.C. § 360k).

Likewise, in the present case, the Seventh Circuit's finding of express preemption centered around APHIS' language in its 1992 Final Rule which states, in pertinent part, as follows:

> "...States are not free to impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency or purity of a product. Similarly, labeling requirements which are different from or in addition to those in the regulations under the Act may not be imposed by the States."

App. A, A-7-8; App. D, A-50,54.

As it plainly appears from the foregoing excerpts and as already acknowledged by the Seventh Circuit below, the

language used in § 360k of the MDA and in APHIS' Final Rule is indistinguishable "in any meaningful way". App. A, A-17. However, this Court held that such language is insufficient to preempt state law causes of action, whereas, in conflict with this Court's decision, the Seventh Circuit held that such language is sufficient to preempt such claims. *Id.*; *Medtronic*, slip op. at 14-19 (opinion of Stevens, J.).

In clear conflict with the fundamental legal principles established by this Court in *Medtronic*, the Seventh Circuit held that it was "not persuaded" that the term "requirements" reflects only an intent to preempt state regulation or similar positive enactments, and instead held that state common law actions impose "additional requirements" on animal vaccines. App. A, A-14,17. To the contrary, this Court, in holding that the "singularly odd word" used by Congress, namely "requirement", was *not* sufficient to preclude all state common-law damages claims, stated that the word requirement "appears to presume that the State is imposing a specific duty upon the manufacturer", and since the use of the word "requirement" in the Federal Act "refer[s] only to statutory and regulatory law that exists pursuant to the [Federal Act] itself, [this] suggest[s] that the pre-empted "requirements" established or continued by states also refer primarily to positive enactments of state law." *Medtronic*, slip op. at 15, 17 (opinion of Stevens, J.)(emphasis added).

Moreover, the Seventh Circuit's decision that "APHIS' preemption statement is clear and comprehensive" is completely at odds with this Court's ruling in *Medtronic* which stated that the mirrored preemption provision in the MDA is "highly ambiguous" and does not clearly signal an "intent to

deprive states of any role in protecting consumers." App. A, A-13; *Medtronic*, slip op. at 3 (Breyer, J., concurring); *Medtronic*, slip op. at 17 (opinion of Stevens, J.). To the contrary, APHIS' own regulations actually evince the allowance of traditional state damages claims as indicated by the following APHIS regulation:

> "Labels...may not include disclaimers of merchantability, fitness..., or responsibility for the product."

9 C.F.R. § 112.2(b) (emphasis added); App. D, A-49. This regulation would have no meaning unless state law actions could be maintained.

On the issue of the preemptive scope of the term "requirements", the Seventh Circuit is also in conflict with this Court's decision in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), by interpreting the preemptive scope of that case much more broadly than intended by this Court. *Medtronic* makes it clear that the *Cipollone* case is not as far-reaching as the Seventh Circuit applied it below. *Cipollone* involved a statute with a much narrower preemptive effect on potential remedies than in the MDA and, likewise, than in the mirrored language of APHIS' Final Rule. *Medtronic*, slip op. at 15-17 (opinion of Stevens, J.). Unlike the statute which was involved in *Cipollone*, an interpretation of the word "requirements", as it is used in the MDA and in APHIS' Final Rule, to preempt state causes of action would "require far greater interference with state legal remedies [than in *Cipollone*], producing a serious intrusion into state sovereignty while simultaneously wiping out the possibility of

remedy". *Id.* Thus, in *Medtronic*, this Court rejected the manufacturer's argument therein "that by using the term "requirement", Congress clearly signaled its intent to deprive states of any role in protecting consumers from the dangers inherent in many medical devices." *Id.* at 16-17, 29 n.19. Rather, the lack of a remedy for injured parties was strong evidence that Congress could not have intended to preempt state actions for remedies. *Id.* at 14-15. The Seventh Circuit, therefore, is in direct conflict with the legal principles set forth by this Court in *Cipollone* and *Medtronic* by utilizing *Cipollone's* narrow interpretation of the term "requirements" to preempt consumers' remedies for defective animal vaccines.

In further conflict with *Cipollone* which held that the general common-law duties "not to deceive" and "not to make fraudulent statements" were not within the scope of "requirements", the Seventh Circuit expressly held that the term "requirements" does encompass claims for fraud. *Id.* at 29 n.19; App. A, A-20.

Lastly, it is even questionable whether the Seventh Circuit afforded proper weight to APHIS' declaration of preemption since even the dissenting Opinion in *Medtronic* stated that "it is not certain that an agency regulation determining the preemptive effect of any federal statute is entitled to deference. *Medtronic*, slip op. at 4 (O'Connor, J., concurring in part and dissenting in part)(emphasis added).

B. Conflict Relating to the Primary Purpose of VSTA and the MDA

Not only was the MDA's language at issue in *Medtronic* indistinguishable from the language at issue in the present case, but the similarity of purpose of the MDA and of VSTA is also quite evident, thus making the Seventh Circuit's decision even more in conflict with this Court's decision in *Medtronic*. Just as the purpose of VSTA "is to assure that biologics used in the treatment of animals are pure, safe, potent and efficacious", the MDA "was enacted to provide for the safety and effectiveness of medical devices intended for human use." App. D, A-45,53; *Medtronic*, slip op. at 17 (opinion of Stevens, J.)(citing 90 Stat. 539).

In *Medtronic*, this Court made "an examination of the basic purpose of the [MDA] as well as its history" and determined that, although there was some reflection of concerns to "protect innovations in device technology from being stifled by unnecessary restrictions", the legislative history indicated "that any fears regarding regulatory burdens were related more to the risk of additional federal and state regulation rather than the danger of pre-existing duties under common law." *Medtronic*, slip op. at 17-18 (opinion of Stevens, J.)(emphasis added). This Court discovered no reference in the MDA's legislative history of any fear that product liability actions would hamper the development of medical devices, and it held that any concern over such protection of the industry "was far outweighed by concerns about the primary issue motivating the MDA's enactment:

the safety of those who use medical devices." *Id.* (emphasis added).

Like the MDA, the legislative history of VSTA reflects absolutely no fear of state product liability actions hampering the innovation of animal vaccines or burdening interstate commerce in any manner. App. D, A-45. Rather, it is clear that the only purpose of the 1985 amendments to VSTA, other than the continued promotion of safety and efficacy, was to bring intrastate vaccines (i.e., vaccines produced and sold within a single state) under USDA control by discarding the artificial distinction between intrastate and interstate vaccines. Prior to the amendments, the "artificial distinction" allowed most intrastate vaccines to escape any official scrutiny. *Id.*

Despite the similarity in purpose of the MDA and VSTA, and despite the fact that VSTA, unlike the MDA, did not even make any reference to any need to protect product innovation, the Seventh Circuit, in clear conflict with this Court's decisions, found that claims relating to animal vaccines were preempted even though it failed to point to anything "in the hearings, the committee reports, or the debates suggesting that any proponent of the legislation intended a sweeping pre-emption of traditional common-law remedies against manufacturers and distributors of defective [animal vaccines]." *Medtronic*, slip op. at 19 (opinion of Stevens, J.)(emphasis added); *See* App. A, A-7; *See also Silkwood v. Kerr-Mcgee Corp.*, 464 U.S. 238, 251 (1984). As stated by this Court, "if Congress intended such a result, its failure even to hint at it is spectacularly odd", and "[i]t is, to say the least, 'difficult to believe that Congress would,

without comment, remove all means of judicial recourse for those injured by illegal conduct'". *Medtronic*, slip op. at 19 (opinion of Stevens, J.); *Silkwood*, 464 U.S. at 251. The Seventh Circuit, however, in conflict with this Court's decisions, apparently did not require any such affirmative showing of Congressional intent to preempt state actions. Indeed, the opinion below, although recognizing the existence of the heightened presumption against the preemption of such actions, quickly disregarded and discounted the presumption's importance. App. A, A-12-13. *Cf. Medtronic*, slip op. at 19 (opinion of Stevens, J.); *Silkwood*, 464 U.S. at 251.

Even if APHIS intended to preempt state claims by the use of the term "requirements", such an action by APHIS would have been outside the scope of the authority delegated to the agency by Congress. Nothing in VSTA nor its legislative history expressly or impliedly suggests that Congress was at all concerned with state common law actions or the preemption thereof. App. D, A-39,45.

C. The Seventh Circuit's Ruling Relating to Compliance With Federal Regulations

Finally, the Seventh Circuit, in ruling that state common law actions were preempted by APHIS, essentially carved out, in dictum, an exception allowing some common law actions to survive if a case involves non-compliance with APHIS regulatory standards. App. A, A-17-19. A similar exception was found by the dissenting justices in the *Medtronic* case. *Medtronic*, slip op. at 5-6 (O'Connor, J., concurring in part and dissenting in part). Likewise, the

Seventh Circuit further held that "when all regulations are complied with and APHIS licenses the vaccine, it is clear that the vaccine satisfies APHIS standards for safety, purity, potency and efficacy", and, accordingly, "state tort claims involving the safety, efficacy, potency or purity of an animal vaccine do *not* survive." App.A, A-18-19.

The Seventh Circuit went on to hold that since Lynnbrook Farms had not alleged non-compliance in its complaint, that the vaccines at issue were thus in compliance with VSTA. App. A, A-18-20. However, as acknowledged by the Seventh Circuit, Lynnbrook Farms' complaint did allege that the vaccines were defective, unreasonably dangerous, unsafe and ineffective. App. A, A-20. These allegations were accepted as true by the Seventh Circuit, and, as stated by this Court in *Medtronic*, "although the precise contours of [the] theory of recovery have not yet been defined ([i.e., since] the pre-emption issue was decided on the basis of the pleadings [only]), it is clear that the...allegations may include claims that [the manufacturer] has, to the extent that they exist, violated [federal] regulations." *Medtronic*, slip op. at 23 (opinion of Stevens, J.). As a result, the Seventh Circuit, once again in conflict with this Court's decision in *Medtronic*, held that claims of non-compliance with federal regulations are not implied in allegations concerning state common law actions. App. A, A-20.

Lynnbrook Farms, like the plaintiffs in *Medtronic*, could not have specifically alleged non-compliance since there is no express or implied private cause of action based on violations of VSTA, just as no such actions exist in the MDA. *Medtronic*, slip op. at 14, 23 (opinion of Stevens,

J.). Furthermore, since the preemption issue in this case was decided at the pleading stage and since no discovery regarding compliance had yet been taken, Lynnbrook Farms had no ability on personal knowledge, other than by alleging in its complaint that the vaccines were unsafe and inefficacious, to develop a factual dispute regarding the compliance issue for summary judgment purposes. Nevertheless, the compliance question was a genuine issue of material fact because it was raised by the Petitioner's allegations which were accepted as true by the Seventh Circuit, thus precluding the award of summary judgment in favor of SmithKline Beecham. Moreover, an award of summary judgment in favor of Smithkline Beecham on the compliance issue essentially nullifies the "exception" to general tort preemption which the Seventh Circuit obstinately created since, in reality, few, if any, plaintiffs could ever survive summary judgment once proof of licensure is presented by a manufacturer.

Regardless, the Seventh Circuit's dependence on "compliance", as it relates to the preemption issue in the present case, even raises a conflict between the dissenting opinion in *Medtronic* and the Seventh Circuit's opinion, which both would preempt claims to the extent that there was compliance with federal regulations. Specifically, *statutory* construction strongly supports Petitioner's view that preemption in this case on the basis of compliance would be entirely inconsistent with the language of § 151 of VSTA. *See* App. D, A-39.

From the plainest meaning of § 151, it is abundantly clear that a corporation may be in violation of the statute for both preparing or selling any worthless, contaminated, dangerous or harmful vaccine ***and*** for preparing or selling a

vaccine that is not under and in compliance with APHIS regulations. In other words, it is undisputable from a fair reading of § 151 that even if a vaccine was prepared under and in compliance with APHIS regulations, a corporation can still be in violation of the statute for selling a vaccine that is worthless, contaminated, dangerous or harmful.

Even assuming that the Seventh Circuit was correct in holding that APHIS intended to preempt cases involving compliance with federal requirements, such an intent by the agency would have been arbitrary, capricious and manifestly contrary to the statute (i.e., § 151) which the agency was authorized to administer since that statute plainly does not exempt a corporation from liability for preparing or selling a worthless, contaminated, dangerous or harmful vaccine even though the vaccine may have been licensed by APHIS and prepared or sold under and in compliance with USDA regulations.

Such a clear Congressional statement concerning the role of compliance as it exists in VSTA does not even exist in the MDA at issue in the *Medtronic* case, yet this Court allowed the common law claims anyway for the reasons aforesaid, thus making even clearer the conflict between the Seventh Circuit's decision and this Court's decision (and even the dissenting Opinion of this Court) in the *Medtronic* case as Lynnbrook Farms' state law claims should have been allowed regardless of whether or not SmithKline Beecham's vaccines were in compliance with APHIS regulations.

D. Summary

Because of the numerous conflicts between the legal principles asserted by the Seventh Circuit's decision in the present case and the fundamental legal principles pronounced in the decisions of this Court, a correction by this Court of the Seventh Circuit's judgment is necessitated.

II.
The Seventh Circuit Has So Far Departed From the Accepted and Usual Course of Judicial Proceedings, and Sanctioned Such a Departure by a Lower Court, As To Call for an Exercise of this Court's Supervisory Power.

Prior to the 1995 District Court decision in the present case, the regulation of animal biologic products by the USDA had never before preempted consumer remedies for animal vaccine-related injuries. In fact, the validity and scope of APHIS' preemption declaration at issue in the Seventh Circuit was one of first impression at the circuit court level. App. A, A-3. Clearly, the District Court and Seventh Circuit decisions run counter to a long history of cases which have allowed such suits against animal vaccine manufacturers.[2]

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[2] *See, e.g., Vasgaard v. Smithkline Beecham Animal Health*, CIV 93-4029 (S.D.S.D. 1995)(decision of Judge John B. Jones denying in all respects Smithkline Beecham's motion for summary judgment based upon APHIS preemption); *Stange v. Norden Laboratories, Inc.*, CIV 91-

Thus, by preempting all traditional state law claims relating to animal vaccines, the Seventh Circuit has so far departed from the accepted and usual course of judicial proceedings in products liability cases, and has sanctioned such a departure by a lower court, as to call for this Court's supervisory power. This Court's guidance is clearly necessary in this case to return state products liability law in the animal vaccine regime to the status quo before *Lynnbrook Farms* and its progeny and to assure that livestock producers, veterinarians and other consumers are once again protected from dangerous and ineffective vaccines as was the original and paramount intent of Congress.

4125 (S.D.S.D.)(case also involving CattleMaster 4 vaccines wherein a jury instruction was given stating that "[c]ompliance with [USDA] Regulations is not, in and of itself, sufficient to exempt a manufacturer from liability..."). *See also Overstreet v. Norden Laboratories, Inc.*, 669 F.2d 1286 (CA6 1982); *Alman Brothers Farms & Feed Mill, Inc. v. Diamond Laboratories, Inc.*, 437 F.2d 1295 (CA5 1971); *Krupp v. Norden Laboratories, Inc.*, 393 N.W.2d 548 (Wis. 1986); *Van Wyk v. Norden Laboratories, Inc.*, 345 N.W.2d 81 (Iowa 1984); *Lovington Cattle Feeders, Inc. v. Abbott Laboratories*, 642 P.2d 167 (N.M. 1982); *Pearson v. Franklin Laboratories, Inc.*, 254 N.W.2d 133 (S.D. 1977); *Colorado Serum Co. v. Arp*, 504 P.2d 801 (Wyo. 1972); *Carter Farms Co. v. Hoffman-Laroche, Inc.*, 492 P.2d 1000 (N.M. 1971); *O.M. Franklin Serum Co. v. C.A. Hoover & Son*, 418 S.W.2d 482 (Tex. 1967); *Chandler v. Anchor Serum Co.*, 426 P.2d 82 (Kan. 1967); *Brown v. Globe Laboratories*, 84 N.W.2d 151 (Neb. 1957).

III.

The Seventh Circuit Has Decided An Important Question of Federal Law That Has Not Been, But Should Be, Settled By This Court.

By granting this petition, this Court could certainly resolve the scope of preemption concerning animal biologic products, and since the present case is now the leading case on the APHIS preemption issue in the United States, it is also the proper vehicle for defining the scope of preemption regarding such products. A decision by this Court in the present case will have widespread effects upon the entire nation as it would substantially impact state sovereignty, the livestock industry, the animal vaccine industry, veterinary medicine, and the consuming public. State civil remedies for injuries relating to all animal biologic products which are regulated by the USDA pursuant to VSTA make this a matter of critical importance not only to the parties involved but also, and more importantly, to all animal vaccine manufacturers, livestock farmers, veterinarians and the consuming public.

Clearly, this case presents an issue of vital importance: whether state law claims involving animal vaccines are preserved or are entirely foreclosed. The underlying issue, of course, is whether VSTA should be used as a preemptive sword for vaccine manufacturers or whether it should be utilized as a protective shield for farmers, veterinarians and the consuming public.

The present case provides this Court with an excellent

opportunity to resolve the scope of APHIS' declaration of preemption of state requirements and whether that declaration encompasses state law claims for remedies relating to injuries from animal biologic products. This is a case of profound significance, as a decision by this Court would affect all animal vaccines and other biologic products licensed under VSTA. Therefore, this Court should grant this petition to review the decision of the Seventh Circuit and to establish certainty in the nation concerning the scope of manufacturers' liability relating to these animal products.

CONCLUSION

For the foregoing reasons, this Court should grant the petition for writ of certiorari.

Respectfully submitted,

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July 22, 1996

APPENDIX A

IN THE

UNITED STATES COURT OF APPEALS

FOR THE SEVENTH CIRCUIT

No. 95-2051
LYNNBROOK FARMS,

Plaintiff-Appellant,

v.

SMITHKLINE BEECHAM CORPORATION,

Defendants-Appellees.

Appeal from the United States District Court
for the Central District of Illinois, Peoria Division.
No. 94-C-1227 – Michael M. Mihm, *Judge.*

ARGUED OCTOBER 27, 1995 – DECIDED MARCH 21, 1996

Before FLAUM, ROVNER and EVANS, *Circuit Judges.*

FLAUM, *Circuit Judge.* This case requires us to determine whether certain state common law causes of action asserted against a manufacturer of animal vaccines are preempted by federal law. Plaintiff, Lynnbrook Farms ("Lynnbrook"), sued Smithkline Beecham Corporation ("SBC") alleging that its cattle were injured and many were killed after being inoculated with animal vaccines

manufactured by SBC. The district court granted summary judgment in favor of SBC, finding Lynnbrook's claims were preempted in their entirety by the United States Department of Agriculture's ("USDA") declaration of preemption issued through its Animal and Plant Health Inspection Service ("APHIS"). We affirm.

I.

The relevant facts are undisputed for purposes of our consideration of the preemption issue. The parties agree that we should accept as true the material allegations contained in Lynnbrook's complaint. In 1992, Lynnbrook vaccinated its cattle with two vaccines manufactured and sold by SBC – CattleMaster 4 and Ultrabac 7/Somubac. Lynnbrook followed all directions and correctly administered the vaccines. Both of the vaccines used by Lynnbrook were specifically licensed by APHIS, the agency charged by the USDA with regulating animal vaccines. 9 C.F.R. § 101.2. Lynnbrook employed the vaccines to prevent its cattle from contracting debilitating or mortal infections and diseases. Notwithstanding the inoculation of Lynnbrook's cattle with these vaccines, the cattle did contract infections and diseases that ultimately killed some of the cattle and debilitated others to an extent that Lynnbrook had to sell or dispose of them at a loss. We assume that the vaccines used were either not effective in preventing the maladies they were designed to guard against, or that the vaccines caused other harm to Lynnbrook's cattle.

Lynnbrook proceeded to sue SBC for the damages it incurred due to the loss of its cattle. Lynnbrook sought

recovery under theories of strict products liability, misrepresentation, false advertising, and breach of implied warranties of merchantability and fitness. SBC moved for summary judgment, contending that Lynnbrook's claims were preempted by APHIS regulations promulgated pursuant to the Virus-Serum-Toxin Act ("VSTA"), 21 U.S.C. §§ 151-159. APHIS declared that "states are not free to impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency or purity of a product." 57 Fed. Reg. 38759 (August 27, 1992). SBC maintained that this express declaration of preemption encompassed all of Lynnbrook's claims. Lynnbrook contested both the validity and the scope of the preemption provision. The district court agreed with SBC and granted summary judgment in its favor on all counts.

II.

We review the district court's grant of summary judgment *de novo. Green v. Shalala,* 51 F.3d 96, 99 (7th Cir. 1995). Summary judgment is appropriate where there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(e). Even accepting the facts as recited above and giving Lynnbrook the benefit of all reasonable inferences (as we must in a summary judgment situation, *see Smith v. Shawnee Library Sys.,* 60 F.3d 317, 320 (7th Cir. 1995)), a finding that Lynnbrook's claims are preempted by federal law would entitle SBC to judgment as a matter of law.

At the outset, we note that the validity and scope of APHIS' preemption statement is one of first impression at

the circuit court level. According to our research, all other courts that have addressed the issue, including the district court below, have reached a conclusion similar to that which we reach today, i.e., that state common law claims of the type asserted in this case are preempted by the APHIS regulation. *See Lynnbrook Farms v. Smithkline Beecham Corp.*, 887 F. Supp. 1100 (C.D. Ill. 1995); *Murphy v. Smithkline Beecham Corp.*, 898 F. Supp. 811 (D. Kan. 1995); *Brandt v. The Marshall Animal Clinic and SmithKline Beecham Corp.*, 540 N.W.2d 870 (Minn. Ct. App. 1995).

A.

The Supremacy Clause of the Constitution declares that "the Laws of the United States . . . shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2. The "Laws of the United States" encompasses both federal statutes and statutorily authorized federal agency regulations. *City of New York v. F.C.C.*, 486 U.S. 57, 63 (1988). With this understanding, the Supreme Court has delineated several avenues by which state law may be superseded by federal law, including when a federal agency acts within the scope of its congressionally delegated authority to preempt state law. *Id.* at 63-64; *Louisiana Public Service Comm'n v. F.C.C.*, 476 U.S. 355, 369 (1986); *Fidelity Federal Savings and Loan Assoc. v. De la Cuesta*, 458 U.S. 141, 152-54 (1982); *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 699-700 (1984). "In proper circumstances, [an] agency may determine that its authority is exclusive and preempt[ ] any state efforts to regulate in the forbidden area." *City of New York*, 486 U.S. at 64. SBC claims that this type of preemption governs this

case. SBC's sole argument is that APHIS expressly preempted all state law claims pursuant to the power delegated to it under VSTA.[1]

In ascertaining whether an agency has acted properly in preempting state law, it is significant to note that an express Congressional authorization to displace state law in the delegating statute is unnecessary. *De la Cuesta*, 458 U.S. at 154. The Supreme Court has warned that a "narrow focus on Congress' intent to supersede state law [is] misdirected." *Id.*; *City of New York*, 486 U.S. at 64. Rather, the proper inquiry is to determine whether the power to preempt is within the bounds of authority granted to the agency by Congress, and if so, whether the agency has acted on this authority. *Id.* The Court has made it clear that the great deference generally afforded agency action is not discarded when the agency uses its delegated discretion to preempt. "Where Congress has directed an administrator to exercise his discretion," and the administrator promulgates regulations intended to preempt state law, "his judgments are subject to judicial review only to determine whether he has exceeded his statutory authority or acted arbitrarily." *De la Cuesta*, 458 U.S. at 154-55; *see also Crisp*, 467 U.S. at 699-700.

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[1] SBC is not claiming that APHIS' comprehensive agency regulation in the field implies preemptive intent on the part of Congress. *See Hillsborough County, Fla. v. Automated Medical Lab., Inc.*, 471 U.S. 707, 713 (1985) (extensive federal scheme of regulation may imply preemption). SBC is relying on APHIS' *express* preemption declaration, not a theory of *implied* preemption. Thus, Lynnbrook's arguments that APHIS' extensive regulations alone, without comprehensive regulation by Congress, cannot lead to implied preemption are inapposite.

Thus, we engage in a three-part analysis to determine if the regulatory actions of APHIS preempt Lynnbrook's state law claims. First, we must ascertain whether the power to preempt is within the authority delegated to the USDA and APHIS by Congress and is a rational exercise of that authority. If so, we then ask whether APHIS intended its regulations to preempt state common law claims. Finally, if APHIS did seek to preempt state common law, we consider whether the regulations preempt the specific causes of actions asserted by Lynnbrook.

B.

In order to answer the first question, we examine the congressional mandate that forms the basis of the agency's authority. VSTA requires that all animal vaccines produced in the United States and all establishments that manufacture such vaccines be licensed by the USDA. 21 U.S.C. § 154. The Act also broadly confers on the USDA the authority to "make and promulgate from time to time such rules and regulations as may be necessary to prevent the preparation [and] sale . . . of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals. . . . " *Id.* The USDA has delegated this responsibility and authority to APHIS. 9 C.F.R. § 101.2. APHIS, in turn, has promulgated an extensive regulatory scheme governing the design, manufacture, distribution, testing, and labelling of animal vaccines. *See* 9 C.F.R. §§ 101-24.

Prior to 1985, several courts held that the scope of VSTA, and hence the application of APHIS regulations,

was limited to products made and sold in interstate commerce. In other words, VSTA did not grant the USDA and APHIS the authority to regulate animal vaccines manufactured and sold within an individual state. *See Animal Health Institute v. U.S. Dept. of Agriculture*, 487 F. Supp. 376 (D. Colo. 1980); *Grand Lab., Inc. v. Harris*, 644 F.2d 729 (8th Cir. 1981), *cert. denied*, 456 U.S. 927 (1982). In response, Congress amended VSTA in 1985 to clearly place both interstate and intrastate vaccines within the ambit of federal control. 21 U.S.C. § 151; S. Rep. No. 145, 99th Cong., 1st Sess. 338-39 (1985), *reprinted in* 1985 *U.S.C.C.A.N.* 1676, 2004-05. The amendments reflect the Congressional finding that federal regulation was "necessary to prevent and eliminate burdens on commerce and to effectively regulate such commerce." 21 U.S.C. § 159.

The legislative history supporting the VSTA amendments also evinces an unquestionable congressional intent to create national, uniform standards for the preparation and sale of animal vaccines. S. Rep. No. 145 at 339. Congress found that animal agriculture has "changed drastically" since the original 1913 passage of VSTA, including the development of "truly national markets." *Id.* It also noted that the industry recognized the need for national standards. *Id.* Congress thus concluded that uniform, federal standards would better serve livestock owners, veterinarians, and the American public. *Id.*

In reaction to the VSTA amendments, APHIS issued the declaration of preemption relied upon by SBC. The declaration states in relevant part:

> *[W]here safety, efficacy, purity, and potency of biological products are concerned, it is the agency's intent to occupy the field.* This includes, but is not

> limited to the regulation of labeling. Under VSTA, Congress clearly intended that there be national uniformity in the regulation of these products.
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> * * *
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> *APHIS . . . does not agree that States should be allowed to add various restrictions* . . . based upon a need to protect domestic animals or the public health, interests or safety. Any restrictions, other than those which are necessary to address a local disease condition, should be Federally imposed so that they are uniform nationwide.
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> * * *
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> *States are not free to impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product. Similarly, labeling requirements which are different from or in addition to those in the regulations under the Act may not be imposed by the States.* Such additional or different requirements would thwart the Congressional intent regarding uniform national standards, and would usurp USDA's authority to determine which biologics are pure, safe, potent and efficacious.

57 Fed. Reg. 38758, 38759 (August 27, 1992) (emphasis added).

We find that APHIS acted rationally and within the scope of the authority granted to it by Congress in issuing the above statement seeking to preempt state law. Congress granted the USDA and APHIS the broad regulatory power to promulgate and enforce "such rules and regulations as may be necessary" to prevent the production and sale of any "worthless, contaminated, dangerous

or harmful" animal vaccines. Congress also delegated to the USDA and APHIS the responsibility to eliminate "undue burdens" on commerce in this area, and toward that end, to establish a national, uniform regulatory scheme. It is apparent that APHIS' congressional mandate is to ensure safe and effective vaccines while at the same time minimize undue burdens on interstate commerce that often accompany varied state regulation. Given these powers and responsibilities, APHIS was acting rationally, and well within its congressionally delegated discretion, in creating a complex statutory scheme governing the safety, efficacy, purity, and potency of animal vaccines and in pronouncing this scheme to be the exclusive law in the area. The Supreme Court has held that:

> if the agency's choice to preempt "represents a reasonable accommodation of conflicting policies that were committed to the agency's care by the statute, we should not disturb it unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned."

City of New York, 486 U.S. at 64 (quoting *United States v. Shimer*, 367 U.S. 374, 383 (1961)); *De la Cuesta*, 458 U.S. at 154. The instant case of preemption reflects a prime example of such an accommodation. Nothing in the legislative history of either VSTA or its amendments indicates that APHIS' actions would not be congressionally sanctioned. On the contrary, the course chosen serves only to further VSTA's purposes – further indicating that the agency was acting within its authority and not acting arbitrarily. *See De la Cuesta*, 458 U.S. at 159. Thus we

decline to disturb the agency's judgment to preempt state law.

Our conclusion is bolstered by several Supreme Court cases that have upheld agency decisions to preempt state law under similarly expansive congressional grants of authority. In *City of New York*, the Court upheld the FCC's power to preempt state and local cable television quality standards, citing the FCC's plenary authority to "[m]ake such rules and regulations and prescribe such restrictions and conditions . . . as may be necessary to carry out" the Commission's statutory purposes. 486 U.S. at 66-67; *see also Crisp*, 467 U.S. at 699-700. In support of its decision, the Court noted Congress' stated objectives to "establish a national policy concerning cable communications" and to "minimize unnecessary regulation that would impose an undue economic burden on cable systems." *City of New York*, 486 U.S. at 61 (quoting 47 U.S.C. §§ 521(1), (6) (1982)).

The Court similarly found that the Federal Home Loan Bank Board could preempt state common law restrictions on due-on-sale practices, as Congress authorized the Board "under such rules and regulations as it may prescribe, to provide for the organization, incorporation, examination, operation, and regulation" of federal savings and loan associations. *De la Cuesta*, 458 U.S. at 170 (quoting 12 U.S.C. § 146(a)(1)). The *De la Cuesta* Court found it significant that Congress' delegation placed no limits on the Board's authority to regulate the lending practices of federal savings and loans and included the power to create and regulate a "uniform system of [savings and loan] institutions where there are not any now." *Id.* at 161, 166. The grant of authority to the USDA and

APHIS under VSTA is no less broad than the power delegated to the FCC and the Federal Home Bank Loan Board. And like those agencies, APHIS has been charged with establishing a uniform, national regulatory scheme.

Lynnbrook apparently acknowledges that Congress granted APHIS the authority to preempt state *regulations* concerning animal vaccines, yet questions APHIS' power to preempt state *tort actions*. Lynnbrook argues that this power is lacking based on the absence of any express authority to preempt state tort law in VSTA. However, as we have already noted, a specific congressional authorization is not a prerequisite to the validity of an agency's preemption decision. The Court has clearly stated that "[f]ederal regulations have no less preemptive effect than federal statutes. . . . A preemptive regulation's force does not depend on express congressional authorization to displace state law. . . . " *De la Cuesta,* 458 U.S. at 153-54.

Lynnbrook also relies on prior caselaw preserving state tort claims in the area of human vaccines to argue that APHIS' delegated authority is limited to preemption of positive regulations. These cases are all distinguishable in important respects. Several of the cases invoked the National Childhood Vaccine Injury Act (42 U.S.C. § 300aa-1 *et seq.*) and the Vaccine Compensation Amendments (26 U.S.C. § 9510) in finding no preemption of state tort claims.[2] However, in these acts Congress explicitly

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[2] *Abbot v. American Cyanamid Co.*, 844 F.2d 1108 (4th Cir.), *cert. denied*, 488 U.S. 908 (1988); *Graham v. Wyeth Lab.*, 666 F. Supp. 1483 (D. Kan. 1987), and *Foyle v. Lederle Lab.*, 674 F. Supp. 530 (E.D.N.C. 1987).

preserved state tort claims for human vaccine related injuries. *See Abbot*, 844 F.2d at 1109 (4th Cir. 1988). The remaining cases cited by Lynnbrook involved FDA regulations;[3] yet the FDA has never expressed any intent to preempt state tort law. On the contrary, the FDA has expressly preserved state tort labelling claims. *Bansemer*, 1990 WL 132579 at *3. Thus, these cases do not persuade us that there is a congressionally intended distinction in VSTA between the power to preempt state regulations and the power to preempt state tort claims.

Lynnbrook finally invokes the presumption against preemption and the heightened presumption in areas that have traditionally been the province of the states, such as health and safety. *Abbot*, 844 F.2d at 1112. This presumption, however, can be overcome by an agency's clear declaration of intent to preempt state law. *Hillsborough County, Fla. v. Automated Medical Lab., Inc.*, 471 U.S. 707, 715-16 (1985) (noting that presumption governs unless preemption "was the clear and manifest purpose of Congress. . . . Of course, the same principles apply where, as here, the field is said to have been preempted by an agency. . . . "). Thus, if APHIS' declaration of preemption clearly encompasses state tort claims (which is our next inquiry), the presumption against preemption offers Lynnbrook no shelter.

We further note that, where similarly broad grants of authority have been involved, the Supreme Court has

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[3] *Bansemer v. Smith Lab., Inc.*, 1990 WL 132579 (E.D. Wis. 1988); *Hoppe v. G.D. Searle & Co.*, 779 F. Supp. 1413 (S.D.N.Y. 1991); *Ferrigno v. Eli Lilly & Co.*, 420 A.2d 1305 (N.J. Super. Ct. 1980); and *Stevens v. Parke, Davis & Co.*, 507 P.2d 653 (Cal. 1973).

never intimated a distinction between agency authority to preempt state law generally and the authority to preempt state common law. *See De la Cuesta*, 458 U.S. at 152-67; *Crisp*, 467 U.S. at 698-705; *City of New York*, 486 U.S. at 63-69. On the contrary, the *De la Cuesta* Court, without hesitation, upheld agency preemption of a state common law rule – a state regulation or statute was not involved. 458 U.S at 148-49.

Moreover, it is significant that in this case Congress was concerned with establishing national uniform standards for animal vaccines. The Supreme Court has recognized that state tort law can impose standards in a manner similar to positive enactments. *See Cipollone v. Liggett Group*, 112 S. Ct. 2608, 2620 (1992) ("state regulation can be as effectively exerted through an award of damages as through some form of preventive relief"). State tort actions can therefore be as much of a threat to national uniformity as affirmative state regulation. Thus, without any congressional indication to the contrary, it follows that Congress included within its grant of preemption power, the power to preempt state common law. Lynnbrook's argument in this case essentially creates a distinction without a meaningful difference. In sum, we are confident that if APHIS intended to preempt state common law, it was acting within its congressionally delegated authority.

C.

As set forth above, APHIS' preemption statement is clear and comprehensive. In an effort to fulfill its mandate to create a national, uniform system of regulations,

APHIS announced it intended to "occupy the field" concerning "the safety, efficacy, purity and potency of biological products." Toward this goal, APHIS decisively stated that "[s]tates are not free to impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product." Lynnbrook argues that this statement reflects only an intent to preempt state regulation of animal vaccines or similar positive enactments, but not an intent to preempt state common law actions such as those brought by Lynnbrook. We are not persuaded.

First, APHIS chose language that mirrors preemption language in federal statutes that has been held by the Supreme Court, this court, and many other courts, to preempt both state regulations and common law damages actions. In *Cipollone v. Liggett Group*, 112 S. Ct. 2608 (1992), the Supreme Court interpreted the preemption provision in the Public Health Cigarette Smoking Act of 1969, which amended the earlier Federal Cigarette Labeling and Advertising Act of 1965. The 1969 provision provided:

> *No requirement or prohibition* based on smoking and health shall be imposed under state law with respect to the advertising and promotion of any cigarettes the packages of which are labelled in conformity with the provision of this Act.

Id. at 2617.[4] The petitioners in *Cipollone* made the same argument that Lynnbrook advances here, maintaining

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[4] The Court also interpreted the original preemption provision in the 1965 Act. That provision stated:

> (a) No statement relating to smoking and health, other than the statement required by section 4 of this

that the provision was not intended to preempt state common law causes of action. The Court disagreed, finding "such an analysis [ ] at odds with the plain words of the 1969 Act and with the general understanding of common law damages actions." *Id.* at 2620. The Court continued: "The phrase 'no requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common law rules." The Court thus rejected the petitioner's argument and held that the provision preempted common law actions. *Id.* at 2621. The Court warned, however, that the clause should not be taken as a blanket preemption of all common law claims. *Id.* The Court continued its analysis to determine which claims fell under the specific language of the clause. *Id.*

Following the Supreme Court's lead, we and other circuit courts (as well as many district courts) have held that language similar to that in *Cipollone*, and substantially the same as the APHIS preemption provision, encompasses common law actions. For instance, in *Shaw v. Dow Brands, Inc.*, 994 F.2d 364 (7th Cir. 1993), we were called upon to determine the scope of the preemption

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Act, shall be required on any cigarette package.

(b) No statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.

Cipollone, 112 S. Ct. at 2616. Finding this language much more narrow and precise than the language in the 1969 provision, the Court held the prior language was not intended to preempt state tort laws. *Id.* at 2619.

language in the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136v(b). The act stated that "[s]uch State shall not impose . . . any requirements for labeling or packaging in addition to or different from those required under this subchapter." *Id.* at 370. With *Cipollone* as our touchstone, we found that the *Cipollone* language of "[n]o requirements or prohibitions" was "just another way of saying a [s]tate shall not impose . . . any requirements," and we therefore held that plaintiff's strict liability and negligence failure to warn claims were preempted by FIFRA. *Id.* at 371. Six other circuits have reached similar conclusions. *See, e.g., Taylor AG Industries v. Pure-Gro,* 54 F.3d 555 (9th Cir. 1995); *Bice v. Leslie's Poolmart,* 39 F.3d 887 (8th Cir. 1994); *MacDonald v. Monsanto Co.,* 27 F.3d 1021 (5th Cir. 1994); *Worm v. American Cyanamid Co.,* 5 F.3d 744 (4th Cir. 1993); *King v. E.I. DuPont De Nemours & Co.,* 996 F.2d 1346 (1st Cir.), *cert. dismissed,* 114 S. Ct. 490 (1993); *Papas v. Upjohn Co.,* 985 F.2d 516 (11th Cir.), *cert. denied,* 114 S. Ct. 300 (1993). More recently, we have held that language in the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a), proscribing "any requirement . . . different from, or in addition to," those established pursuant to the MDA extended to preempt certain common law actions. *Mitchell v. Collagen Corp.,* 67 F.3d 1268, 1276 (7th Cir. 1995); *see also Slater v. Optical Radiation Corp.,* 961 F.2d 1330, 1333 (7th Cir.), *cert. denied,* 506 U.S. 917 (1992). Many circuits agree. *See, e.g., Michael v. Shiley, Inc.,* 46 F.3d 1316 (3rd Cir.), *cert. denied,* 116 S. Ct. 67 (1995); *Reeves v. AcroMed Corp.,* 44 F.3d 300 (5th Cir.),

cert. denied, 115 S. Ct. 2251 (1995); *National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988 (8th Cir. 1994).[5] Lynnbrook has not distinguished the language used by APHIS in any meaningful way from the language used in FIFRA or the MDA.[6] In the face of this strong and consistent authority, we are compelled to reach the same conclusion we reached in *Shaw*. If common law actions cannot survive under the 1969 cigarette law, FIFRA or the MDA, then common law actions imposing additional requirements on animal vaccines cannot survive the reach of the APHIS provision. *See Shaw*, 994 F.2d at 371.

Although the caselaw supporting our conclusion is substantial, we are even more confident that APHIS intended to include common law damages actions within the scope of its preemption after reviewing the only official APHIS statement (to our knowledge) explaining its intent in adopting the quoted regulation. In a letter dated December 22, 1995, the Acting Administrator of the agency explained, that the intent in "promulgating the rule was, and continues to be, to preempt States from

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[5] Similar language in the Federal Hazardous Substances Act ("FHSA"), 15 U.S.C. § 1261, has also been held to preempt common law damages actions. *See Moss v. Parks Corp.*, 985 F.2d 736 (4th Cir.), *cert. denied*, 113 S. Ct. 2999 (1993).

[6] Lynnbrook's only attempt to avoid the result dictated by these precedents is to claim that, in the cases of FIFRA and the MDA, the language was employed by Congress in a statute, not by an agency in a regulation. However, as we have now noted several times, this is of no moment, as "federal regulations have no less preemptive effect than federal statutes." *De la Cuesta*, 458 U.S. at 153-54.

imposing requirements either through statutes, regulations, *or other means* that are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product." (emphasis added).[7] The letter further stated that "[w]e did not intend to preempt common law actions for damages *arising from noncompliance with USDA regulatory standards.*" (emphasis added). Interestingly, both sides claim the letter unequivocally supports their position.

We must agree with SBC that the correspondence confirms the interpretation that APHIS intended certain state tort claims to be preempted. Contrary to Lynnbrook's argument that APHIS only intended to preempt positive enactments, the agency included in its preemptive scope additional requirements dictated by States via "regulations, statutes, or other means." The phrase "or other means" clearly encompasses state tort claims. Moreover, APHIS' letter signals that state tort claims are available when APHIS regulatory standards are violated or disregarded. The natural conclusion to draw from this statement is that when APHIS regulations are heeded, state tort claims involving the safety, efficacy, potency, or purity of an animal vaccine do *not* survive. This dichotomy follows from the preemption language chosen by APHIS, as it is precisely when APHIS regulations have

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[7] Following oral argument, Lynnbrook submitted a motion to take judicial notice of the letter from APHIS, along with two other letters. The motion is granted as to the December 22, 1995 APHIS letter; the motion is denied as to the other two letters. The parties have also made several other post oral argument motions, all of which we deny.

been satisfied that a common law action imposes requirements in addition to, or different from, those mandated by APHIS.[8] Where noncompliance is involved, a common law action could simply serve to impose the standards of APHIS. Thus, it is evident that APHIS intended to preempt common law claims relating to areas under its regulatory control (namely the safety, purity, potency, and efficacy of vaccines) which would impose additional or different requirements on vaccines, i.e., common law claims involving regulated areas in cases where the manufacturer has complied with all APHIS regulations and standards. The last step is to determine if Lynnbrook's claims fall within this preempted group of claims.

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[8] APHIS regulations extensively govern the manufacture and marketing of vaccines in order to ensure their safety, purity, potency and efficacy. For instance, manufacturers are required to submit an "Outline of Production" detailing every step in the design, testing, production, and packaging of all animal vaccines. *See* 9 C.F.R. §§ 114.8-9. The outline is a precondition to licensure by APHIS, and no changes may be made to the outline without approval from APHIS. 9 C.F.R. § 102.5(d)(1). In addition, the regulations provide an elaborate testing protocol that must be administered by the manufacturer or by APHIS. *See* 9 C.F.R. §§ 113.25-55; 9 C.F.R. §§ 113.64-.332. Further, APHIS requires all animal vaccines to list certain information on all labels, including the container label, the carton label, and any product insert, circular or leaflet. 9 C.F.R. § 112. The label must be approved by APHIS in writing prior to licensure. *Id.* Thus, when all regulations are complied with and APHIS licenses the vaccine, it is clear that the vaccine satisfies APHIS standards for safety, purity, potency, and efficacy.

D.

It is undisputed that SBC manufactured and marketed Cattlemaster 4 and Ultrabac 7/Somubac according to all APHIS regulations. This is not a case involving noncompliance. Both vaccines have met APHIS standards for safety, purity, potency, and efficacy. Thus, if Lynnbrook's claims relate to these qualities, seeking to impose additional or different requirements in these areas, they are preempted. We find that this describes all of Lynnbrook's claims.

Counts I and VII of Lynnbrook's complaint sound in strict products liability (one for each vaccine), apparently based on the theory that the vaccines were defective and unreasonably dangerous. If these claims are allowed to proceed they would impose a duty on SBC regarding at least the safety (if not also the efficacy, purity and potency) of the cattle vaccines different from the requirements enforced by APHIS. Counts II and III state claims for breach of implied warranties of fitness for a particular purpose and of merchantability. These actions clearly implicate the efficacy and safety of the vaccines and would likewise impose higher or different standards on SBC.

Counts IV and V of the complaint allege fraudulent misrepresentation and false advertising under the common law and the Illinois Consumer Fraud and Deceptive Business Practices Act. Lynnbrook alleges that SBC falsely represented that the vaccines were safe and effective when it knew they were not. In order to succeed on these claims, a jury would have to find that the vaccines were not safe and effective. However, APHIS has already

declared the products safe and efficacious by its standards. Thus a different standard would be enforced. In addition, these counts could be viewed as failure to warn claims, *see King v. Collagen Corp.*, 983 F.2d 1130, 1136 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993), which would result in labeling requirements distinct from those dictated by APHIS. The same is true of Counts VI and VIII, which allege strict liability failure to warn claims (one for each vaccine).

APHIS has licensed both Cattlemaster 4 and Ultrabac 7/Somubac and thus declared the vaccines are safe, efficacious, potent and pure by its measures. By bringing claims that clearly implicate and call into question these qualities, Lynnbrook seeks to "impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency or purity of a product." The claims are thus preempted in their entirety.

III.

We recognize that the conclusion we reach today leaves Lynnbrook and similar plaintiffs no remedy for the injuries and losses that they have suffered. However, we are not at liberty to reverse the judgments of an agency acting within its congressionally delegated authority. It is evident not only that APHIS intended claims such as those brought by Lynnbrook to be preempted, but also that Congress granted APHIS the power to act on those intentions. Therefore we AFFIRM the district court's order granting summary judgment in SBC's favor.

A true Copy:

Teste:

Clerk of the United States Court of Appeals for the Seventh Circuit

APPENDIX B

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF ILLINOIS

LYNNBROOK FARMS, Plaintiff, v. SMITHKLINE BEECHAM CORPORATION and NORDEN LABORATORIES, Defendants.	)	Case No. 94-1227

ORDER

(Filed Mar. 30, 1995)

This matter comes before the Court on Defendants' Motion to Dismiss [7] and Motion for Summary Judgment [15]. Pursuant to Local Rule 1.4, the Motion to Dismiss was referred to Magistrate Judge Robert J. Kauffman. While reviewing the motion, Magistrate Kauffman determined that due to the existence of the affirmative defense of federal preemption, the Motion to Dismiss should not be ruled upon until the parties had briefed the preemption issue. (Order dated October 12, 1994). The Defendants subsequently filed their Motion for Summary Judgment, which relies solely on the issue of federal preemption in support of the motion. This Court heard oral argument on the motion on February 24, 1995 and gave the parties leave to file proposed findings of fact and conclusions of law. (Transcript of 2/24/95 hrg. at 22-23). Defendants timely filed their Proposed Findings

of Fact and Conclusions of Law [23]. Plaintiff has apparently elected not to file a proposed pleading. The Court has reviewed the pleadings, affidavits and other materials submitted to the Court in support of and in opposition to the Motion for Summary Judgment and, for the reasons set forth herein, GRANTS the Motion for Summary Judgment [15] and finds the Motion to Dismiss DENIED [7] as moot.

Findings of Fact

Plaintiff, Lynnbrook Farms, is a general partnership organized under the laws of Illinois. (Amended Complaint at 1). Defendant Norden Laboratories merged into Smithkline Beacham on or about January 1, 1992. (Answer to Amended Complaint at 3). Prior to the merger, Norden Laboratories existed as a Delaware corporation. (Amended Complaint at 2). Defendant Smithkline Beecham is a corporation organized under the laws of Pennsylvania. *Id.* at 1-2. The Defendants will hereafter be referred to as "SBC." The parties have stipulated that the amount in controversy is in excess of $50,000. (Answer to Amended Complaint at 2). This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332.

The Amended Complaint, filed June 6, 1994, alleges that Defendants manufacture animal vaccines for ultimate sale to the public in the State of Illinois. (Amended Complaint at 3). Defendants deny that their animal vaccines were sold to various firms for distribution to the public, answering instead that the "vaccines in question were subject to use, evaluation and administration by

veterinary physicians under the learned intermediary doctrine." (Answer to Amended Complaint at 4).

The vaccines at issue in this suit are *CattleMaster4 and Ultrabac7/Somubac. (Amended Complaint at 3, 11). The United States Department of Agriculture ("USDA") has licensed each of the vaccines, *CattleMaster4 under USDA License No. 1187.21 and Ultrabac7/Somubac under USDA License No. 4723.00. (Affidavit of Cyril G. Gay, D.V.M., Ph.D. at ¶¶ 3-9). Plaintiff contends that it purchased these vaccines from the Miller Company in Morton, Illinois. (Amended Complaint at 3, 11). According to the Amended Complaint, Plaintiff intended to use these vaccines on its cattle to prevent debilitating disease and/or mortal infection. *Id.* at 3, 12. Plaintiff alleges that notwithstanding its use of the vaccines, some of its cattle contracted debilitating disease and died. *Id.* at 4, 12-13. Other cattle had to be disposed of at a loss due to the extent of debilitations. *Id.* The Amended Complaint asserts that Plaintiff took all recommended precautions, including refrigerating the vaccines, and despite these actions the vaccines did not perform as they were intended. *Id.* at 4, 12. Plaintiff further asserts that these vaccines proximately caused the debilitation and death of its cattle. *Id.*

The Amended Complaint presents eight counts. In Counts I and VII, Plaintiff asserts that SBC is liable, under a strict liability theory, for the defective, dangerous, and inefficacious nature of *CattleMaster 4 and Ultrabac7/Somubac, respectively. Counts II and III contain allegations that SBC breached implied warranties of fitness for a particular purpose and merchantability under the Illinois Uniform Commercial Code, 810 ILCS 5/1-101, *et seq.*

Count IV states a claim for fraudulent misrepresentation. Count V alleges that SBC violated the Illinois Consumer Fraud and Deceptive Practices Act, 815 ILCS 505/1, *et seq.*, through the advertising and promotion of *CattleMaster4. In Counts VI and VII, Plaintiff contends that the *CattleMaster4 and Somubac vaccines were defective in that the product labeling on the vaccines failed to warn against certain alleged dangers arising out of their use.

Conclusions of Law

Summary judgment will be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). Once the moving party has borne its burden of identifying those portions of the pleadings, answers to interrogatories, etc., that demonstrate there is no genuine issue of material fact, the nonmoving party must come forward with specific facts showing that there is a genuine issue for trial. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87, 106 S.Ct. 1348, 1356 (1986). Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial. *Id.* at 587 (citations omitted). When considering a motion for summary judgment, courts must give the benefit of all inferences to the party opposing the motion and examine the record in the light most favorable to that party. *United States v. Diebold, Inc.*, 369 U.S. 654, 655, 82 S.Ct. 993, 994 (1962); *Sarsha v. Sears, Roebuck & Co.*, 3 F.3d 1035, 1038 (7th Cir. 1993).

In this matter, the Court gives the benefit of all inferences to the Plaintiff, for purposes of the Motion for Summary Judgment, regarding Plaintiff's allegations that it purchased the vaccines, *CattleMaster4 and Ultrabac7/ Somubac, for use on its cattle; that it properly utilized these vaccines; and that its cattle contracted debilitating disease and either died or had to be disposed of at a loss. All this being true, however, will not permit the Plaintiff to survive summary judgment if the Virus-Serum-Toxins Act ("VSTA") preempts Plaintiff's state common law and statutory claims.[1] In the event that this Court finds VSTA to preempt state law, Plaintiff, for all the injury sustained by it, will have no remedy at law.

The presumption against preemption, especially where the state law being usurped is a traditional state police power, is well established. *California v. ARC America Corp.*, 490 U.S. 93, 100, 109 S.Ct. 1661, 1665 (1989); *Maryland v. Louisiana*, 451 U.S. 725, 746, 101 S.Ct. 2114, 2129 (1981) ("Consideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law"); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 1152 (1947) ("we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress") (citations omitted). The same presumption

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[1] All animal vaccines marketed in the United States are regulated by the USDA pursuant to authority delegated to it by Congress under VSTA. 21 U.S.C. §§ 151-158. USDA's Animal and Plant Health Inspection Service ("APHIS") is responsible for administering VSTA. 9 C.F.R. § 101.2; *Foundation on Economic Trends v. Lyng*, 680 F.Supp. 10, 11 (D.D.C. 1988).

applies when an agency acts to preempt the field. *Hillsborough County, Fla. v. Automated Medical laboratories, Inc.*, 471 U.S. 707, 715, 105 S.Ct. 2371, 2376 (1985). In instances where agency preemption is alleged, however, a "narrow focus on Congress' intent to supersede state law [is] misdirected," as "[a] preemptive regulation's force does not depend on express congressional authority to displace state law." *Fidelity Federal Sav. and Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 154, 102 S.Ct. 3014 (1982).

Congress may act to preempt state law in three ways. Express preemption exists where Congress has legislated in clear and unequivocal terms, found within the text of the statute, that an act preempts state law. *See, e.g., Cipollone v. Liggett Group, Inc.*, 112 S.Ct. 2608, 2617-20 (1992). Implied preemption may be found (1) where state law actually conflicts with an act of Congress, or (2) where federal legislation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it. *Hines v. Davidowitz*, 312 U.S. 52, 67, 61 S.Ct. 399, 404 (1941). Finally, state law may be preempted by federal regulations, *Hillsborough, supra*, at 713, where a federal agency, acting within the scope of its congressionally delegated authority, acts to preempt state law. *Fidelity Federal Sav. and Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153-54, 102 S.Ct. 3014, 3022-23 (1982) (citations omitted); *City of New York v. F.C.C.*, 486 U.S. 57, 63-64, 108 S.Ct. 1637, 1642 (1988) (citing *Louisiana Public Service Com'n v. F.C.C.*, 476 U.S. 355, 106 S.Ct. 1890, 1898-99 (1986)).[2]

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[2] The regulations of a federal agency will preempt state or local laws which conflict with or frustrate the purposes of the regulations. *City of New York, supra*, at 64. In certain situations,

In the case at bar, Defendants have eschewed the express and implied preemption arguments, relying solely upon agency preemption to support its Motion for Summary Judgment. (Tr. of 2/24/95 Oral Argument at 3-4). Thus, this Court must determine first whether the agency which regulated cattle vaccines, APHIS, was acting within its congressionally delegated authority. *City of New York, supra,* at 63-64. Once this Court finds that APHIS was acting within its grant of authority, it must determine whether the language APHIS chose in promulgating its regulations is sufficiently broad to preempt each of Plaintiff's claims. *Id.* at 66.

Under VSTA, all animal vaccines sold in the United States, and all establishments at which animal vaccines are produced, must be licensed by the USDA. 21 U.S.C. § 154 (West Supp. 1994). Within USDA, licensure of animal vaccines and vaccine-producing establishments is regulated by the USDA's APHIS. 9 C.F.R. § 101.1, *et seq.* This Court finds that Congress has delegated broad authority to the USDA and APHIS to promulgate and enforce "such rules and regulations as may be necessary" for the preparation and sale of animal vaccines in the United States. 21 U.S.C. § 154 (West Supp. 1994).

In 1980 and 1981, several federal court opinions issued which found that the breadth of VSTA was limited to "interstate" commerce. *See Animal Health Institute v. U.S. Dept. of Agriculture,* 487 F.Supp. 376 (D.Colo. 1980); *Grand Laboratories, Inc. v. Harris,* 644 F.2d 729 (8th Cir.

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the agency may declare its authority exclusive, which then requires finding any state or local effort to regulate within the area preempted. *Id.*

1981), *on rehearing*, 660 F.2d 1288 (8th Cir. 1981), *cert. denied*, 456 U.S. 927 (1982). These decisions found that the USDA did not have the authority to regulate the production and sale of products made within a single state. *Animal Health Institute*, 487 F.Supp. at 379; *Grand Laboratories*, 644 F.2d at 731, 660 F.2d at 1289. Congress responded to these cases by amending VSTA to eliminate any distinction between "intrastate" and "interstate" manufacture and distribution of animal vaccines. S.Rep.No. 99-145, 99th Cong., 1st Sess. at 338-9 (1985), *reprinted in* 1985 *U.S. Code Congressional & Administrative News*, 1676, 2004-5. This congressional action placed the manufacture and sale of all animal vaccines under the control of the United States federal government. 21 U.S.C. § 151.

The legislative history surrounding the 1985 amendments to VSTA indicates Congress' intent to create a national, uniform standard for the preparation and sale of animal vaccines. S.Rep.No. 99-145. In this excerpt of legislative history, Congress noted that an "intrastate/interstate" distinction no longer exists for comparable products such as animal drugs, food additives, medical devices, or pesticides. *Id.* Congress concluded that due to the drastic changes in animal agriculture since 1913, including the presence of "truly national markets," a uniform regulatory standard would better serve "livestock owners, veterinarians, and the American public." *Id.*

As a basic for comparison, this Court studied the decision in *City of New York*, in which the Supreme Court decided whether the Federal Communications Commission ("FCC") had properly acted within its congressionally delegated power in preempting state and local cable

television quality standards. 486 U.S. at 66. The Court turned to both the Cable Communications Policy Act of 1984, 47 U.S.C. §§ 521-559 (1982 ed., Supp. IV), and the Communications Act of 1934 to analyze the breadth of power the FCC had been granted by Congress. *Id.* at 60-62. In an earlier decision, *Capital Cities Cable, Inc. v. Crisp*, the Court had found that Congress authorized the FCC "to regulate all aspects of interstate communication by wire or radio." 467 U.S. 691, 700, 104 S.Ct. 2694 (1984). According to the *Crisp* Court, this authority extended to "all regulatory actions 'necessary to ensure the achievement of the Commission's statutory responsibilities.' " *Id.* (quoting *F.C.C. v. Midwest Video Corp.*, 440 U.S. 689, 706, 99 S.Ct. 1435, 1444 (1979)). Shortly after the *Crisp* decision, Congress enacted the 1984 Cable Act, which states that Congress intended to "establish a national policy concerning cable communications" and to "minimize unnecessary regulation that would impose an undue economic burden on cable systems." 47 U.S.C. §§ 521(1), (6) (1982 ed., Supp IV).

The language in the 1985 amendments to VSTA are no less broad than the grant of authority to the FCC in the 1934 and 1984 Acts. The language Congress chose in enacting the 1985 amendments to VSTA indicates its intent to grant the USDA broad powers "necessary to prevent and eliminate burdens on . . . commerce and to effectively regulate . . . commerce." 21 U.S.C. § 159. Congress gave the Secretary of Agriculture the power to "make and promulgate from time to time such rules and

regulations as may be necessary to prevent the preparation, sale . . . or shipment . . . of any worthless, contaminated, dangerous or harmful virus, serum, toxin, or analogous product. . . . " 21 U.S.C. § 154.

Having found that the congressional grant of power to USDA's APHIS was broad enough to include the authority to preempt state laws, this Court must now turn to the second prong of this analysis, which is whether the language that APHIS chose in promulgating its regulations is sufficiently broad to preempt each of Plaintiff's claims. *De la Cuesta, supra,* at 153-54. "[W]here Congress has directed an administrator to exercise his discretion, his judgments are subject to judicial review only to determine whether he has exceeded his statutory authority or acted arbitrarily." *Id.*

SBC asserts that APHIS has expressly construed the 1985 amendments to VSTA as reserving to the federal government the exclusive responsibility for the safety, efficacy, purity, potency, and labeling of animal vaccines. Further, SBC seeks to invoke the rule that unless an agency's decision to preempt state law is arbitrary or capricious, "it must be given controlling weight by the reviewing court." *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.,* 467 U.S. 837, 845, 104 S.Ct. 2778 (1984).

In the August 27, 1992 Federal Register, APHIS articulated its interpretation of the 1985 amendments, in relevant part, as follows:

> Where safety, efficacy, purity, and potency of biological products are concerned, it is the agency's intent to occupy the field. This

> includes, but is not limited to the regulation of labeling. Under [the 1985 amendments to VSTA], Congress clearly intended that there be national uniformity in the regulation of these products.
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> * * *
>
> APHIS . . . does not agree that States should be allowed to add various restrictions . . . based upon a need to protect domestic animals or the public health, interests or safety. Any restrictions, other than those which are necessary to address a local disease condition, should be Federally imposed so that they are uniform nationwide.
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> * * *
>
> [S]tates are not free to impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product. Similarly, labeling requirements which are different from or in addition to those in the regulations under the Act may not be imposed by the States. Such additional or different requirements would thwart the Congressional intent regarding uniform national standards, and would usurp USDA's authority to determine which biologics are pure, safe, potent and efficacious.

57 *Fed. Reg.* 38758, 38759 (August 27, 1992).

The Court must turn to the analysis set out in *Chevron* to determine whether or not this interpretation of the 1985 amendments is to be given controlling weight. 467 U.S. 837, 842-43. As Congress has not directly spoken to the issue of preemption, the Court must decide whether

APHIS' declaration of preemption is based upon a permissible construction of VSTA. *Chevron*, 467 U.S. at 843-44. APHIS' interpretation can be found to be based upon a permissible construction, thus entitled to controlling weight, if it is not arbitrary, capricious or manifestly contrary to VSTA.[3] *Id.*

The language of the amendments, including those sections aforementioned which grant the Secretary of Agriculture the authority to "make and promulgate such rules and regulations as may be necessary to prevent the preparation, sale, barter, exchange or shipment . . . of any worthless contaminated, dangerous or harmful . . . serum, toxin, or analogous product," 21 U.S.C. § 154, "to prevent and eliminate burdens on [interstate] commerce and to effectively regulate such commerce," 21 U.S.C. § 159, allow the permissible interpretation that APHIS may preempt state law. The choice to preempt state law represents "a reasonable accommodation of conflicting policies that were committed to the agency's care by the statute," *United States v. Shimer*, 367 U.S. 374, 382, 81 S.Ct. 1554 (1961), in that it would be difficult to prevent or eliminate burdens on interstate commerce if each of the 50 states could impose different regulations on animal vaccines. Thus, APHIS' reading is neither arbitrary nor capricious.

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[3] The Supreme Court held in *Morton v. Ruiz*, 415 U.S. 199, 231, 94 S.Ct. 1055, 1072 (1974), that "[t]he power of an administrative agency to administer a congressionally created . . . program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress."

Further, it is congruous with VSTA's purpose of regulating the safety, efficacy, purity, potency, and labeling of animal vaccines.

Finally, the Court must analyze the various claims of Plaintiff to determine whether the legal duty that is the predicate of the common law damages counts, *Cipollone, supra,* at 2621, would impose a requirement upon the Defendants which is "different from, or in addition to, those imposed by the USDA regarding the safety, efficacy, potency, or purity of a product." *Cipollone, supra,* at 2621; 57 *Fed. Reg.* 38758, 38759 (August 27, 1992).

It is noteworthy that several Courts of Appeal, including the Seventh Circuit, have previously addressed language similar to that of APHIS' regulations in the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136, *et seq.* Section 136v(b) of FIFRA, entitled Authority of the States, provides as follows:

> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required by this subchapter.

7 U.S.C. § 136v.

The majority of circuits to consider FIFRA's preemptive reach, including the Seventh Circuit, find this language to preempt both positive enactments and common law. *MacDonald v. Monsanto Co.,* 27 F.3d 1021 (5th Cir. 1994); *Bice v. Leslie's Poolmart, Inc.,* 39 F.3d 887 (8th Cir. 1994); *King v. E.I. Dupont De Nemours and Co.,* 996 F.2d 1346 (1st Cir. 1993), *cert. dismissed,* 114 S.Ct. 490 (1993); *Worm v. American Cyanamid Co.,* 5 F.3d 744 (4th Cir. 1993);

Shaw v. Dow Brands, Inc., 994 F.2d 364 (7th Cir. 1993); *Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.*, 981 F.2d 1177 (10th Cir. 1993), *cert. denied*, 114 S.Ct. 60 (1993); *Papas v. Upjohn Co.*, 985 F.2d 516 (11th Cir. 1993), *cert. denied* by *Papas v. Zoecon Corp.*, 114 S.Ct. 300 (1993).

Applying this logic, Counts I and VII of Plaintiff's Amended Complaint, which allege the two vaccines were defective, dangerous, and inefficacious, would impose a duty on SBC regarding the safety, efficacy, potency, or purity of the cattle vaccines which would be in addition to or different from those regulations promulgated by the USDA and enforced by APHIS.

Similarly, Counts II and III allege that SBC breached implied warranties of fitness of a particular purpose and merchantability, respectively. These allegations implicate the safety and efficacy of SBC's cattle vaccines and, as such, are preempted by VSTA.

Counts IV and V state claims for fraudulent misrepresentation and false advertising, alleging that Defendants knew the vaccine *CattleMaster4 was dangerous and lacked efficacy. These claims are inherently failure to warn claims which, if not preempted, would allow a jury to determine that the vaccine was unsafe and/or inefficacious. Thus, a requirement different from or in addition to those set out by APHIS would be imposed upon SBC. These Counts are both preempted.

With regard to the failure to warn claims, Counts VI and VIII, APHIS has expressly stated that "labeling requirements which are different from or in addition to those in the regulations under the Act may not be

imposed by the States." 57 *Fed. Reg.* at 38759. Thus, to the extent that Plaintiff's failure to warn claims would require SBC to alter the labels of its cattle vaccines, they are also preempted.

All this being said, the Court is troubled by the absence of a federal remedy. Based on the breadth of APHIS' congressional grant of authority, the express language of the regulations, and the agency's permissible interpretation of VSTA, however, this Court can come to no other viable conclusion.

Conclusion

For the reasons set forth herein, the Court GRANTS the Defendants' Motion for Summary Judgment in favor of Defendants Smithkline Beecham and Norden Laboratories and against Plaintiff. Lynnbrook Farms, and finds the Motion to Dismiss DENIED as moot.

ENTERED this 30th day of March, 1995.

/s/ Michael M. Mihm
Michael M. Mihm
Chief United States
District Judge

APPENDIX C

United States Court of Appeals
For the Seventh Circuit
Chicago, Illinois 60604

April 22, 1996

HON. JOEL M. FLAUM, Circuit Judge

HON. ILANA D. ROVNER, Circuit Judge

HON. TERENCE T. EVANS, Circuit Judge

LYNNBROOK FARMS, an Illinois General Partnership, Plaintiff-Appellant, No. 95-2051 v. SMITHKLINE BEECHAM CORPORATION, Defendant-Appellee.	] Appeal from the United States District Court for the Central District of Illinois, Peoria Division. No. 94 C 1227 Michael M. Mihm, Chief Judge.

ORDER

On consideration of the petition for rehearing and suggestion for rehearing *en banc* filed in the above-entitled cause on April 3, 1996, by plaintiff-appellant, no judge in active service has requested a vote thereon, and all of the judges on the original panel have voted to deny a rehearing. Accordingly,

IT IS ORDERED that the aforesaid petition for rehearing and suggestion for rehearing *en banc* be, and the same is hereby **DENIED.**

APPENDIX D

CHAPTER 5 – VIRUSES, SERUMS, TOXINS, ANTITOXINS AND ANALOGOUS PRODUCTS

21 U.S.C. § 151. Preparation and sale of worthless or harmful products for domestic animals prohibited; preparation to be in compliance with rules at licensed establishments

It shall be unlawful for any person, firm, or corporation to prepare, sell, barter, or exchange in the District of Columbia, or in the Territories, or in any place under the jurisdiction of the United States, or to ship or deliver for shipment in or from the United States, the District of Columbia, any territory of the United States, or any place under the jurisdiction of the United States, any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals, and no person, firm, or corporation shall prepare, sell, barter, exchange, or ship as aforesaid any virus, serum, toxin, or analogous product manufactured within the United States and intended for use in the treatment of domestic animals, unless and until the said virus, serum, toxin, or analogous product shall have been prepared, under and in compliance with regulations prescribed by the Secretary of Agriculture, at an establishment holding an unsuspended and unrevoked license issued by the Secretary of Agriculture as hereinafter authorized.

(As amended Dec. 23, 1985, Pub.L. 99-198, Title XVII, § 1768(a), 99 Stat. 1654.)

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21 U.S.C. § 152. Importation regulated and prohibited

The importation into the United States of any virus, serum, toxin, or analogous product for use in the treatment of domestic animals, and the importation of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, is prohibited without (1) a permit from the Secretary of Agriculture, or (2) in the case of an article originating in Canada, such permit or, in lieu of such permit, such certification by Canada as may be prescribed by the Secretary of Agriculture.

(As amended Sept. 28, 1988, Pub.L. 100-449, Title III, § 301(d), 102 Stat. 1868.)

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21 U.S.C. § 153. Inspection of imports; denial of entry and destruction

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21 U.S.C. § 154. Regulations for preparation and sale; licenses

The Secretary of Agriculture is hereby authorized to make and promulgate from time to time such rules and regulations as may be necessary to prevent the preparation, sale, barter, exchange, or shipment as aforesaid of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals or otherwise to carry out

this paragraph, and to issue, suspend, and revoke licenses for the maintenance of establishments for the preparation of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, intended for sale, barter, exchange, or shipment as aforesaid.

(As amended Dec. 23, 1985, Pub.L. 99-198, Title XVII, § 1768(b), 99 Stat. 1654.)

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21 U.S.C. § 154a. Special licenses for special circumstances; expedited procedure; conditions; exemptions; criteria

In order to meet an emergency condition, limited market or local situation, or other special circumstance (including production solely for intrastate use under a State-operated program), the Secretary may issue a special license under an expedited procedure on such conditions as are necessary to assure purity, safety, and a reasonable expectation of efficacy. The Secretary shall exempt by regulation from the requirement of preparation pursuant to an unsuspended and unrevoked license any virus, serum, toxin, or analogous product prepared by any person, firm, or corporation –

(1) solely for administration to animals of such person, firm, or corporation;

(2) solely for administration to animals under a veterinarian-client-patient relationship in the course of the State licensed professional

practice of veterinary medicine by such person, firm, or corporation; or

(3) solely for distribution within the State of production pursuant to a license granted by such State under a program determined by the Secretary to meet criteria under which the State –

(A) may license virus, serum, toxin, and analogous products and establishments that produce such products;

(B) may review the purity, safety, potency, and efficacy of such products prior to licensure;

(C) may review product test results to assure compliance with applicable standards for purity, safety, and potency, prior to release to the market;

(D) may deal effectively with violations of State law regulating virus, serum, toxin, and analogous products; and

(E) exercises the authority referred to in subclauses (A) through (D) consistent with the intent of this paragraph of prohibiting the preparation, sale, barter, exchange, or shipment of worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous products.

(Pub.L. 99-198, Title XVII, § 1768(c), Dec. 23, 1985, 99 Stat. 1654.)

21 U.S.C. § 155. Permits for importation

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21 U.S.C. § 156. Licenses conditioned on permitting inspection; suspension of licenses

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21 U.S.C. § 157. Same; inspection daytime or nighttime

Any officer, agent, or employee of the Department of Agriculture duly authorized by the Secretary of Agriculture for the purpose may, at any hour during the daytime or nighttime, enter and inspect any establishment where any virus, serum, toxin, or analogous product for use in the treatment of domestic animals is prepared for sale, barter, exchange, or shipment as aforesaid.

(As amended Dec. 23, 1985, Pub.L. 99-198, Title XVII, § 1768(d), 99 Stat. 1655.)

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21 U.S.C. § 158. Offenses; punishment

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21 U.S.C. § 159. Enforcement; penalties applicable Congressional findings

The procedures of sections 672, 673, and 674 of this title (relating to detentions, seizures and condemnations, and injunctions, respectively) shall apply to the enforcement of this chapter with respect to any product prepared, sold, bartered, exchanged, or shipped in violation of this chapter or a regulation promulgated under this chapter. The provisions (including penalties) of section 675 of this title shall apply to the performance of official duties under this chapter. Congress finds that (i) the products and activities that are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce or the free flow thereof, and (ii) regulation of the products and activities as provided in this chapter is necessary to prevent and eliminate burdens on such commerce and to effectively regulate such commerce.

(Pub.L. 99-198, Title XVII, § 1768(e), Dec. 23, 1985, 99 Stat. 1655.)

LEGISLATIVE HISTORY
P.L. 99-198

[page 338]

Virus-Serum-Toxin Act of 1913

The bill would clarify and update the Virus-Serum-Toxin Act of 1913 (the "VST Act"), the statutory authority for U.S. Department of Agriculture regulation of animal vaccines and related products.

USDA's Animal and Plant Health Inspection Service ("APHIS") has a long and successful history of assuring livestock owners, veterinarians, and the American public that there is an ample supply of safe and effective animal vaccines and other biological products. APHIS carries out its responsibilities pursuant to the VST Act.

But legislation designed to serve the interest of animal agriculture more than seven decades ago has been overtaken by modern events, due to the VST Act's archaic concepts of authority for a Federal regulatory agency, as compared to modern statutes.

Two recent Federal court decisions have created confusion and concern among the producers of animal biological products and those who utilize them. The thrust of these decisions is that USDA has primary regulatory authority over finished products physically moving in interstate commerce, but all other products, such as those made and sold within a single State, are subject only to Food and Drug Administration jurisdiction. These "intrastate" products are not subject to USDA licensure, and FDA has, so far, not asserted its authority over them in a

comprehensive manner. In the meantime, "interstate" products remain firmly under the jurisdiction of USDA.

The narrow "intrastate" versus "interstate" distinction found in the VST Act no longer exists for any class of comparable products. Federal laws make no such distinctions for human-use pharmaceuticals, animal drugs, food additives, color additives, medical devices, processed food, meat and poultry products, or pesticides; all are subject to uniform Federal regulatory standards, whether they cross state lines or not.

[page 339]

Animal agriculture has changed drastically since 1913. One major alteration in the industry is the tremendous increase in interstate movement of animal and animal-derived foods. There are truly national markets for the live animals and their products, while USDA's animal vaccine regulatory program is compelled by law to maintain an artificial distinction between "intrastate" and "interstate" commerce in the products used to treat these animals.

The need for uniform national standards has become recognized widely in recent years. The major national livestock producer groups support these amendments, as does the veterinarians' national association. Furthermore, a number of States have enacted rules permitting only USDA-licensed animal vaccines to be sold or used within their borders.

According to a recent USDA survey, at least 15 States now routinely require that animal biologic products used within their boundaries be licensed by USDA, although some of these States permit certain types of unlicensed vaccines under limited special circumstances. These States are Alabama, Colorado, Florida, Hawaii, Idaho, Louisiana, Michigan, Minnesota, Mississippi, Montana, New York, Oklahoma, Pennsylvania, Utah and Wyoming. When the Oklahoma State Board of Agriculture adopted an "emergency regulation" to this effect in 1981, its justification was "an imminent peril to the public welfare." USDA found that only two States, California and South Dakota, actively regulate "intrastate" animal biologics. It must be assumed, therefore, that "intrastate" animal biologic products are almost entirely free of any official scrutiny in the remaining 33 States.

USDA can effectively control the movement of diseased animals and contaminated food of animal origin through court-authorized seizure and injunctive powers. However, the VST Act presently does not give the Department these essential means for the control of animal vaccines and related products. Expanded regulatory authority for USDA would be meaningless, if the Department did not have the tools needed to bring about compliance. Presently, the only enforcement tool is a criminal misdemeanor prosecution. The bill would give USDA powers comparable to those available to regulate commerce in animals and animal-derived foods such as detention and court-ordered seizure and injunction.

The bill provides licensing exemptions for animal owners and veterinarians, who could continue to produce unlicensed vaccines for use in animals under their care

(although enforcement actions against unsafe or ineffective products would be authorized). Biologics produced in States that have adequate testing/regulatory programs could continue to be marketed "intrastate" under those State programs without USDA licensing. In addition, all other "intrastate" manufacturers would have four years from the date of enactment to phase into the USDA licensing system.

9 C.F.R. § 112.2 Final container label, carton label, and enclosure.

* * *

(b) Labels may also include any other statement which is not false or misleading and may include factual statements regarding variable response of different animals when vaccinated as directed but may not include disclaimers of merchantability, fitness for the purpose offered, or responsibility for the product.

* * *

57 Fed. Reg. 38758 (August 27, 1992)

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9 CFR Part 102

[Docket No. 88-187-2]

Viruses, Serums and Toxins and Analogous Products; Restrictions on Distribution and Use

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends the regulations pertaining to restrictions which may be imposed by States on the distribution and use of veterinary biological products. It also provides a procedure whereby any person may request that Federal restrictions be imposed on such products. The purpose of the final rule is to clarify the regulations with respect to State restrictions on the use and distribution of veterinary biological products, and to specify how a person can request that Federal restrictions be imposed on such products.

EFFECTIVE DATE: This rule is effective September 28, 1992.

FOR FURTHER INFORMATION CONTACT: Dr. David A. Espeseth, Deputy Director. Veterinary Biologics, BBEP, APHIS, USDA, room 838, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, telephone number (301) 436-8245.

SUPPLEMENTARY INFORMATION:

Background

A proposed rule was published on October 19, 1990 (55 FR 42392, Docket No. 88-187); to clarify APHIS' position that restrictions on the distribution and use of Federally licensed veterinary biological products may be imposed by a State or other jurisdiction when such restrictions are based on local disease conditions. Moreover, the proposed rule provided a procedure whereby any person, including a State or other jurisdiction, may request that Federal restrictions be imposed on such products. A 80-day comment period which ended December 18, 1990, was provided for in that proposal.

The Animal and Plant Health Inspection Service (APHIS) received seventeen comments regarding the proposed rule. Comments were received from State animal health authorities, trade associations, a professional association, veterinary hospitals, universities, a biologics manufacturer, and a biologics consultant. APHIS has carefully considered all comments concerning the proposed rule.

Based on the rationale set forth in the proposed rule and this document, APHIS is adopting the provisions of the proposed rule with two minor changes as discussed below for the purposes of clarity.

Fourteen comments were generally in favor of the rule as proposed. Two comments took exception to the rule. One comment indicated that the proposed rule should be strengthened to require States to seek APHIS approval prior to imposing restrictions on distribution

and use of veterinary biologics. The comments are discussed in greater detail below.

Twelve comments agree that, based on local disease conditions, States should have the authority to impose restrictions on the distribution and use of veterinary biological products.

Nine of these comments indicated that because vaccines used in disease control programs require careful tracking, vaccines in these categories should be administered by or under the direction of a veterinarian. APHIS has the authority to require label statements that certain biological products be used under the supervision of veterinarians and has imposed such requirements (see 9 CFR 102.5(e)).

Several commenters requested that the wording in 9 CFR 102.5(e) which currently reads in relevant part " * * * the biological product is restricted to use by veterinarians, or under the *supervision* of veterinarians, or both" be changed to " * * * by or under the *direction* of a veterinarian" (emphasis added). The commenter argued that the change would be consistent with the language used under labeling requirements in accordance with 9 CFR 112.2(d)(1).

This comment is beyond the scope of this rulemaking and therefore will not be considered in this docket. However, the agency will consider whether it is appropriate to make the suggested changes in future rulemaking.

Several commenters also requested that the language in 9 CFR 102.5(e) and (f) be amended to read that restrictions be based on "the protection of animal or human

health and safety," rather than the language currently used: "the protection of domestic animals or the public health, interest, or safety, or both". The commenters stated that "use of the term 'interest' is vague and unacceptable."

The regulation will not be amended based on these comments because the purpose of the Act is to assure that biologics used in the treatment of animals are pure, safe, potent, and efficacious. The public benefits as a result of the successful protection of animals from various diseases, including those which are of great public concern such as rabies. Since safe and effective vaccines and other biologics are in the public interest, APHIS has used this term in the regulations.

Seven commenters indicated that States should have the authority to add to Federal restrictions, as appropriate, based on a need to protect animal or human health and safety so long as such restrictions do not lessen the effect of Federal regulations. APHIS agrees with the comment that States should not be allowed to lessen the effect of Federal restrictions on the distribution and use of veterinary biological products. APHIS, however, does not agree that States should be allowed to add various restrictions, as appropriate, based upon a need to protect domestic animals or the public health, interest, or safety. Any restrictions, other than those which are necessary to address a local disease condition, should be Federally imposed so that they are uniform nationwide.

The legislative history relating to the 1985 amendments to the Act, which extends USDA's authority over veterinary biologics, clearly expresses Congressional

intent that Federal regulation of veterinary biologics is needed to prevent and eliminate burdens on commerce and that there is a need for uniform national standards regarding these products. Therefore, States are not free to impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product. Similarly, labeling requirements which are different from or in addition to those in the regulations under the Act may not be imposed by the States. Such additional or different requirements would thwart the Congressional intent regarding uniform national standards, and would usurp USDA's authority to determine which biologics are pure, safe, potent, and efficacious. However, it has been APHIS' consistent position that individual States may impose certain restrictions on the distribution and use of biological products licensed by USDA based on local disease conditions when such restrictions are made on a product-by-product basis. For example, a State is permitted to restrict distribution of a biological product where a particular disease does not exist in the State and where use of the biological product would make it difficult to distinguish between exposed and vaccinated animals.

Likewise, a State is permitted to restrict use of a product to licensed veterinarians when a disease exists in the State and the State has an active eradication program. In this case, such a restriction may be necessary to ensure the effectiveness of the eradication program.

Other commenters asked that only States and not other jurisdictions should be allowed to impose the restrictions in § 102.5(d)(2), and that the restrictions be

imposed on a case-by-case basis. The term "other jurisdiction" must remain in the regulations because the term "States" does not include places under Federal jurisdiction. Insofar as other localities are concerned, it is APHIS' position that any restrictions based on local disease conditions within a State should be imposed by or in conjunction with State authorities in order to prevent a proliferation of conflicting restrictions.

Two commenters disagreed that any person should be able to request that Federal restrictions be imposed on biologics. The commenters were concerned that such a provision in the rules might encourage individuals to attempt to restrict unnecessarily the use and availability of veterinary biological products. With respect to the provision in the final rule which allows any person to request APHIS to impose a Federal restriction on biologics, we do not believe that such requests should be limited to State agencies. The commenters' concern is unwarranted because APHIS would be making the decision regarding such requests, and unnecessary restrictions would not be imposed on products.

Two minor changes are made to § 102.5(d)(2) for clarity. The term "Deputy Administrator" is changed to "Administrator" to be consistent with APHIS administrative policy and the term "shall" is changed to "may".

Executive Order 12291, Executive Order 12778, and Regulatory Flexibility Act

We are issuing this final rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the

Department it has been determined that this final rule will have an effect on the economy of less than $100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions, and will not have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. It is not intended to have retroactive effect. This rule does not preempt any State or local laws, regulations, or policies, where they are necessary to address local disease conditions or eradication programs. However, where safety, efficacy, purity, and potency of biological products are concerned, it is the agency's intent to occupy the field. This includes but is not limited to the regulation of labeling. Under the Act, Congress clearly intended that there be national uniformity in the regulation of these products. There are no administrative proceedings which must be exhausted prior to any judicial challenge to the regulations under this rule. Under certain circumstances, States may restrict the distribution and use, within their own borders, of veterinary biological products licensed by APHIS. The current regulation, however, has caused some confusion regarding the extent of such restrictions. The final rule

clarifies the regulation. It also provides a procedure whereby any person can request that Federal restrictions be imposed on a veterinary biologic.

(2)

Supreme Court, U.S.
FILED
AUG 22 1996
CLERK

No. 96-125

In The

Supreme Court of the United States

October Term, 1995

LYNNBROOK FARMS,
an Illinois General Partnership,

Petitioner,

vs.

SMITHKLINE BEECHAM CORPORATION,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Seventh Circuit

RESPONDENT SMITHKLINE BEECHAM CORPORATION'S BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

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79 pp

QUESTION PRESENTED

Are Petitioner's state law claims for harm to animals purportedly caused by animal vaccines, as set forth in its Amended Complaint, preempted by federal law where the United States Department of Agriculture ("USDA"), acting within the scope of its delegated authority under the Virus-Serum-Toxin Act, 21 U.S.C. §§ 151-159, clearly expressed its intent to preempt all state law – including common law damages actions – which would impose requirements different from or in addition to those imposed by USDA regarding the safety, efficacy, purity, potency or labeling of animal vaccines and where it is undisputed that the vaccines at issue complied with USDA requirements?

PARTIES TO THE PROCEEDINGS

Pursuant to Rule 29.6, respondent SmithKline Beecham Corporation states that it has the following non-wholly owned subsidiaries in the United States: SmithKline Beecham Holdings Corp. and SmithKline Beecham Consumer Healthcare L.P. Respondent's parent company is SmithKline Beecham plc, a public limited company incorporated under the laws of England.

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RESPONDENT'S BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

Respondent SmithKline Beecham Corporation ("SBC") respectfully requests that this Court deny the petition of Lynnbrook Farms ("Lynnbrook") for a Writ of Certiorari which seeks review of the opinion issued below in this case by the United States Court of Appeals for the Seventh Circuit.

OPINIONS AND ORDERS BELOW

The opinion of the United States Court of Appeals for the Seventh Circuit is reported at 79 F.3d 620 (7th Cir. 1996), and included in Pet. App. at A-1. The opinion of the United States District Court for the Central District of Illinois, Peoria Division, is reported at 887 F. Supp. 1100 (C.D. Ill. 1995), and included in Pet. App. at A-23.

JURISDICTIONAL STATEMENT

The United States Court of Appeals for the Seventh Circuit entered judgment on March 21, 1996. (Pet. App. A-1) Lynnbrook filed a petition for rehearing and suggestion for rehearing *en banc* on April 3, 1996, which the court denied on April 22, 1996. (Pet. App. A-38)

Lynnbrook filed a petition for a Writ of Certiorari with this Court on July 22, 1996. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL PROVISION, STATUTES AND REGULATIONS INVOLVED

The supremacy clause of the United States Constitution, Article VI, cl. 2 is included in Resp. App. at A-32.

The Virus-Serum-Toxin Act ("VSTA"), 21 U.S.C. §§ 151-159 (1913) (amended 1985) is included in Resp. App. at A-33. The legislative history to the 1985 amendments to VSTA, S. Rep. No. 99-145, 99th Cong. 1st Sess. at 338-39 (1985) *reprinted in* 1985 U.S. Code Congressional &

Administrative News 1676, 2004-5, is included in Pet. App. at A-45.

The regulations promulgated pursuant to VSTA by the United States Department of Agriculture's Animal and Plant Health Inspection Service ("APHIS"), 9 C.F.R. Parts 101-124, have been lodged with the Clerk of Court. APHIS' declaration of preemption, 57 Fed. Reg 38758, 38759 (Aug. 27, 1992), is included in Pet. App. at A-50. Correspondence regarding the scope of APHIS' declaration of preemption from Acting Administrator of APHIS, Terry L. Medley, to Senator Paul D. Wellstone, dated December 22, 1995, is included in Resp. App. at A-29.

STATEMENT OF THE CASE

The Declaration of Preemption

This case involves the validity and application of an *express* declaration of preemption of state law made by a federal agency. Pursuant to the Virus-Serum-Toxin Act ("VSTA"), 21 U.S.C. §§ 151-159 (1913) (amended 1985), the United States Department of Agriculture ("USDA") is authorized to promulgate "such rules and regulations as may be necessary" to prevent the manufacture, sale and distribution of any "worthless, contaminated, dangerous or harmful" animal vaccines. (Resp. App. 34-35) Within USDA, the Animal and Plant Health Inspection Service ("APHIS") is responsible for administering VSTA.

Following two court decisions holding that VSTA did not apply to the production and sale of animal vaccines made and sold within a single state, Congress in 1985 amended VSTA to place both "intrastate" and "interstate" animal vaccines under federal control. (S. Rep. No. 99-145, 99th Cong. 1st Sess. at 338-39 (1985), *reprinted in* 1985 U.S. Code Congressional & Administrative News 1676, 2004-5; Pet. App. A-45; 21 U.S.C. § 151; Resp. App. 33) In doing so, Congress declared that federal regulation of all animal vaccines was necessary to prevent and eliminate burdens upon interstate and foreign commerce. (21

U.S.C. § 159; Resp. App. 38-39) In the legislative history, Congress also expressed its unequivocal desire for "uniform national standards" for animal vaccines manufactured and sold in the United States. (S. Rep. No. 99-145, 99th Cong. 1st Sess. at 338-39; Pet. App. A-46)

Citing its intent to accomplish these precise congressional goals, APHIS made the following declaration of preemption of state law on August 27, 1992, in response to comments made during a rulemaking:

> Seven commenters indicated that States should have the authority to add to Federal restrictions, as appropriate, based on a need to protect animal or human health and safety so long as such restrictions do not lessen the effect of Federal regulations. APHIS agrees with the comment that States should not be allowed to lessen the effect of Federal restrictions on the distribution and use of veterinary biological products. *APHIS, however, does not agree that States should be allowed to add various restrictions as appropriate, based upon a need to protect domestic animals or the public health, interest, or safety. Any restrictions, other than those which are necessary to address a local disease condition should be Federally imposed so that they are uniform nationwide.*
>
> The legislative history relating to the 1985 amendments to the Act, which extends USDA's authority over veterinary biologics, clearly expresses Congressional intent that Federal regulation of veterinary biologics is needed to prevent and eliminate burdens on commerce and that there is a need for uniform national standards regarding these products. Therefore, *States are not free to impose requirements which are different from or in addition to those imposed by USDA regarding the safety, efficacy, potency, or purity of a product. Similarly, labeling requirements which are different from or in addition to those in the*

> *regulations under the Act may not be imposed by the States.* Such additional or different requirements would thwart the Congressional intent regarding uniform national standards, and would usurp USDA's authority to determine which biologics are pure, safe, potent and efficacious.
>
> * * *
>
> *[W]here safety, efficacy, purity and potency of biological products are concerned, it is the agency's intent to occupy the field. This includes but is not limited to the regulation of labeling.* Under the Act, Congress clearly intended that there be national uniformity in the regulation of these products.

(57 Fed. Reg. 38758, 38759 (Aug. 27, 1992); Pet. App. A-53 – A-56) (Emphasis added.)

In response to a congressional inquiry in December 1995, APHIS confirmed its intent to preempt *all* state law – including common law damages actions – which would impose requirements upon animal vaccine manufacturers different from or in addition to those imposed by APHIS regarding the safety, efficacy, purity, potency and labeling of animal vaccines. (Resp. App. 29-30) The confirmation of the scope of APHIS' declaration of preemption came after three courts, including the district court in this case, held that federal law preempted the plaintiffs' state law claims in actions alleging harm to cattle by vaccines where it was undisputed that the vaccines at issue fully complied with APHIS' requirements. (*Lynnbrook Farms v. SmithKline Beecham Corp.*, 887 F. Supp. (C.D. Ill. 1995); Pet. App. A-23; *Brandt v. The Marshall Animal Clinic*, 540 N.W.2d 870 (Minn. Ct. App. 1995); *Murphy v. SmithKline Beecham Animal Health*, 898 F. Supp. 811 (D. Kan. 1995)).

Following the Minnesota Court of Appeals decision in *Brandt*, the plaintiffs in that case enlisted the aid of Senator Paul D. Wellstone of Minnesota in an effort to cause APHIS to change course. By letter dated December 6, 1995, Senator Wellstone officially requested APHIS to "clarify" its preemption declaration – *i.e.*, to specify that

state tort actions were *not* preempted – before December 26, 1995, so that the Brandts could wield APHIS' "clarification" to their benefit when seeking discretionary review of the Minnesota Court of Appeal's decision before the Minnesota Supreme Court. In correspondence dated December 22, 1995, the Acting Administrator of APHIS, Terry L. Medley, responded to Senator Wellstone's inquiry. (Resp. App. 29-30) Referring to APHIS' final rule of August 27, 1992, which contained APHIS' declaration of preemption, Mr. Medley stated in part:

> *We stated in that rule that in order to maintain uniform national standards regarding veterinary biological products (including labeling) States are not free to impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product.* We promulgated this rule in response to regulatory actions by certain States which intended to impose requirements concerning USDA licensed veterinary biological products which were different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency or purity of a product.
>
> *Our intent in promulgating the rule was, and continues to be, to preempt states from imposing requirements either through statutes, regulations, or other means, that are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency or purity of a product. Such requirements would include, but are not limited to, production, testing, distribution or labeling requirements.* We did not intend to preempt common law action damages arising from noncompliance with USDA regulatory standards.

(Resp. App. 29-30) (Emphasis added.)

Proceedings Before The District Court

Petitioner Lynnbrook filed this action on May 18, 1994, in the United States District Court for the Central District of Illinois, Peoria Division. The district court exercised jurisdiction under 28 U.S.C. § 1332.

In its Amended Complaint, Lynnbrook contended that its cattle were injured after being vaccinated in mid-1992 with two animal vaccines manufactured and sold by SBC – *CattleMaster 4 and Ultrabac 7/Somubac. (Resp. App. 1-16) According to Lynnbrook, the vaccines were either inefficacious in that they failed to protect against diseases that they were designed to counteract or alternatively, unsafe in that the vaccines caused other harm to the cattle. (*Id.*) Lynnbrook sought recovery against SBC upon separate theories of strict liability, negligence, misrepresentation, false advertising, and breach of implied warranties of merchantability and fitness. (*Id.*)

On November 2, 1994, SBC moved for summary judgment in its favor on all counts of the Amended Complaint on the grounds that federal law preempted all of the state law claims asserted by Lynnbrook. In support of its motion for summary judgment, SBC submitted the Affidavit of Cyril G. Gay, D.V.M., Ph.D. (Resp. App. 17-24) Dr. Gay testified that each of the vaccines at issue was specifically licensed by the USDA through APHIS. (Resp. App. A-20 – A-21) Through the licensure process and through post-licensure testing and evaluation, APHIS necessarily determined that each of the vaccines involved in the litigation satisfied all of APHIS' requirements for purity, safety, potency and efficacy. (Resp. App. 21) In addition, APHIS specifically approved in writing the text, layout and design of all labeling, packaging and product inserts for the vaccines. (Resp. App. 21)

Lynnbrook submitted *no evidence* in its resistance to the motion for summary judgment to controvert the testimony of Dr. Gay that the vaccines at issue fully satisfied all of APHIS' standards for safety, efficacy, purity, potency and labeling. Instead, Lynnbrook argued that

compliance with APHIS standards was neither dispositive nor a defense to liability because APHIS' requirements were intended to be only "minimum standards." Moreover, Lynnbrook stipulated that *no* discovery was required to adjudicate the preemption issue and invited SBC to seek a court order staying discovery during the pendency of the motion. (Resp. App. 25-26) SBC agreed and the district court entered such an order on February 15, 1995. (Resp. App. 27-28)

On March 30, 1995, Chief Judge Michael M. Mihm of the United States District Court for the Central District of Illinois, Peoria Division, entered findings of fact and conclusions of law, granted SBC's motion for summary judgment and entered final judgment in SBC's favor, dismissing with prejudice Lynnbrook's Amended Complaint in its entirety. (Pet. App. A-23)

Applying controlling precedents of this Court, the district court analyzed the validity and scope of APHIS' declaration of preemption. (Pet. App. at A-26 – A-29) Specifically, the district court considered: (1) whether the agency intended to preempt state law, including common law damages actions; (2) whether the agency acted within the scope of its delegated authority and acted neither arbitrarily, capriciously nor manifestly contrary to the statute the agency is authorized to administer; and (3) whether the plaintiff's state law claims fall within the scope of the declaration of preemption. (Pet. App. at A-29 – A-37)

As to the first question, the district court concluded that APHIS intended to preempt all state law, including state tort actions, which would impose requirements different from or in addition to those imposed by APHIS regarding the safety, efficacy, potency, purity and labeling of animal vaccines. In finding that APHIS unambiguously expressed its intent to preempt state law, the district court reasoned that the agency both explicitly stated its intent "to occupy the field" and patterned its "no requirements different from or in addition to" language after

other express statutory preemption provisions such as the Public Health Cigarette Smoking Act of 1969, 15 U.S.C. § 1334, the Federal Insecticide, Fungicide & Rodenticide Act, 7 U.S.C. § 136v(b), and the Medical Device Amendments to the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 360k(a), which dozens of courts have held preempt common law causes of action falling within the scope of the particular area of law preempted. (Pet. App. at A-32 – A-36)

Second, the district court found that APHIS acted within the scope of its congressionally delegated authority, even though Congress had been silent on the issue of preemption. In finding that APHIS had sufficient authority to preempt state law, the district court pointed to (1) the authority delegated to the agency to promulgate "such rules and regulations as may be necessary" to prevent the manufacture, sale and distribution of any "worthless, contaminated, dangerous or harmful" animal vaccines; (2) the authority delegated to the agency to prevent and eliminate burdens upon and to regulate effectively interstate commerce; and (3) Congress' expressed desire in the legislative history for "uniform national standards" for the manufacture and sale of animal vaccines in the United States. The district court reasoned that the broad authority granted by Congress in VSTA to APHIS compared favorably with other federal programs, most notably the 1934 and 1984 Communications Acts, which this Court has held authorized the FCC to expressly preempt certain areas of state law. Because permitting each of the 50 states through tort law to impose requirements upon animal vaccines different from or in addition to those imposed by APHIS would undermine Congress' call for uniform national standards and the elimination of undue burdens upon commerce, the district court determined that APHIS' declaration of preemption is neither arbitrary, capricious nor manifestly contrary to VSTA. (Pet. App. at A-29 – A-32)

Having determined that APHIS' declaration of preemption was entitled to controlling weight, the district court held that each claim contained in the Amended Complaint was barred. The district court reasoned that each claim, if accepted by a jury, would by necessity impose different or additional requirements upon SBC regarding the safety, efficacy, purity, potency or labeling of the vaccines at issue because it is undisputed that APHIS found the vaccines to have fully satisfied all of its requirements in these areas. (Pet. App. at A-35 – A-37)

Proceedings Before The Seventh Circuit

The United States Court of Appeals for the Seventh Circuit affirmed the district court's decision by applying the same three-part inquiry and relying upon the same reasons as the district court, with one notable addition. Following both the district court's decision and oral argument before the Seventh Circuit, APHIS clarified the scope of its declaration of preemption on December 22, 1995 in response to a congressional inquiry. Both Lynnbrook and SBC asked the Seventh Circuit to take judicial notice of the December 22, 1995 correspondence from Acting Administrator of APHIS, Terry L. Medley, to Senator Wellstone.

The Seventh Circuit granted the motions to take judicial notice of the December 22, 1995 letter from APHIS. The Seventh Circuit agreed with SBC that the correspondence confirmed the interpretation that APHIS intended to include certain state tort claims within the scope of the declaration of preemption:

> Contrary to Lynnbrook's argument that APHIS only intended to preempt positive enactments, the agency included in its preemptive scope additional requirements dictated by States via 'regulations, statutes or other means.' The phrase 'or other means' clearly encompasses state tort claims. Moreover, APHIS' letter signals that state tort claims are available when APHIS

> regulatory standards are violated or discarded. The natural conclusion to draw from this statement is that when APHIS regulations are heeded, state tort claims involving the safety, efficacy, potency, or purity of an animal vaccine do *not* survive. This dichotomy follows from the preemption language chosen by APHIS, as it is precisely when APHIS regulations have been satisfied that a common law action imposes requirements in addition to, or different from, those mandated by APHIS. Where non-compliance is involved, a common law action could simply serve to impose the standards of APHIS. Thus, it is evident that APHIS intended to preempt common law claims relating to areas under its regulatory control (namely the safety, purity, potency and efficacy of vaccines) which would impose additional or different requirements on vaccines, *i.e.*, common law claims involving regulated areas in cases where the manufacturer has complied with all APHIS regulations and standards.

(Pet. App. at A-18 – A-19) (Emphasis in original.)

In response to SBC's motion for taking judicial notice of the December 22, 1995 correspondence, Lynnbrook attempted to raise a belated argument that a genuine issue of material fact existed concerning whether the vaccines at issue complied with APHIS standards. Not only did Lynnbrook fail to adduce any evidence regarding non-compliance at the district court, counsel for Lynnbrook during oral argument at the Seventh Circuit conceded that, if the court were to find that APHIS' declaration covered state tort claims, all of the counts of the Amended Complaint would be preempted – *i.e.*, that Lynnbrook's claims sought to establish requirements "different from or in addition to" those imposed by APHIS regarding the safety, efficacy, purity, potency and labeling of the vaccines at issue. SBC objected to Lynnbrook's

attempt to raise an issue it had waived and the Seventh Circuit stated in its opinion that:

> This is not a case involving non-compliance. Both vaccines have met APHIS standards for safety, purity, potency, and efficacy.

(Pet. App. at A-20) Because all of the claims asserted in the Amended Complaint would impose additional or different requirements in these areas, the Seventh Circuit held that federal law preempted Lynnbrook's claims in their entirety. (Pet. App. at A-20 – A-21)

On April 22, 1996, the Seventh Circuit denied Lynnbrook's petition for rehearing and suggestion for rehearing *en banc*. The Seventh Circuit also denied Lynnbrook's motion to stay issuance of mandate on April 29, 1996.

Following the decision of this Court on June 26, 1996 in *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996), Lynnbrook filed a motion for the Seventh Circuit to reconsider either its judgment of March 21, 1996, affirming the district court's judgment or its order of April 22, 1996, denying Lynnbrook's petition for rehearing and suggestion for rehearing *en banc*. In its memorandum of law, Lynnbrook argued that this Court's decision in *Lohr* justified reconsideration of this matter, a withdrawal of the Seventh Circuit's judgment and a reversal of the district court's judgment.

On July 8, 1996, after apparently recognizing its procedural error in filing a motion to reconsider, Lynnbrook filed a motion to recall mandate, again asserting that this Court's decision in *Lohr* required the Seventh Circuit to recall mandate. The Seventh Circuit ordered SBC to respond to the motion. In its response, SBC argued that *Lohr* does not call into serious question the correctness of the Seventh Circuit's decision in this case. Upon consideration of the parties' substantive arguments, which included the application of *Lohr* to the facts in this case, the Seventh Circuit denied the motion to recall mandate on August 5, 1996. (Resp. App. at A-31)

REASONS FOR DENYING THE WRIT

Lynnbrook's petition for a Writ of Certiorari should be denied because the question presented is not ripe. At this time, there is no conflict among lower court decisions involving the identical question presented here. In three cases involving the same facts and claims, each court unanimously upheld the validity of APHIS' express declaration of preemption and found that the plaintiffs' claims fall within the scope of the declaration of preemption. The analysis and reasoning applied and the conclusions reached by the courts are the same.

There is also no conflict with relevant decisions of this Court. The Seventh Circuit correctly applied the analyses set forth by this Court for determining the validity of an agency's declaration of preemption and for determining that Lynnbrook's claims fall within the scope of the area of law preempted. In addition, the Seventh Circuit considered and rejected Lynnbrook's arguments that this Court's decision in *Lohr* requires a withdrawal of the Seventh Circuit's judgment and a reversal of the district court's judgment.

Accordingly, there is no reason to remand this case to the Seventh Circuit for reconsideration in light of *Lohr*. Because no court, other than the Seventh Circuit, has considered this issue in light of *Lohr*, it is too early for this Court to consider the question presented. Rather, it would be wiser to allow lower courts to apply *Lohr* to similar cases, allowing the possibility of differing views to emerge and possibly result in a conflict that does not exist at this time. For these reasons, the Court should summarily deny Lynnbrook's petition for a Writ of Certiorari.

I. There Is No Conflict Among Lower Court Decisions Involving The Identical Question Presented Here.

Because the decision of the Seventh Circuit in this case is consistent with final judgments on the same matter entered by other federal and state courts, there is no conflict for this Court to resolve at this time. *See Lynnbrook Farms v. SmithKline Beecham Corp.*, 887 F. Supp. 1100 (C.D. Ill. 1995), *aff'd* 79 F.3d 620 (7th Cir. 1996); *reh'g and suggestion for reh'g en banc denied* (April 22, 1996); Pet. App. at A-1; A-23; *Murphy v. SmithKline Beecham Animal Health Group*, 898 F. Supp. 811 (D. Kan. 1995), *appeal dismissed* (10th Cir. Nov. 14, 1995); *Brandt v. The Marshall Animal Clinic*, 540 N.W.2d 870 (Minn. Ct. App. 1995), *review denied* (Minn. Feb. 9, 1996). In denying petitions for a Writ of Certiorari, this Court has repeatedly cited a lack of conflict among lower courts as a reason to wait for an issue to receive further study before it is addressed by this Court:

> My vote to deny certiorari in these cases does not reflect disagreement with Justice Marshall's appraisal of the importance of the underlying issue. . . . I believe that further consideration of the substantive and procedural ramifications of the problem by other courts will enable us to deal with the issue more wisely at a later date. There is presently no conflict of decision within the federal system. . . . In my judgment it is a sound exercise of discretion for the Court to allow the various States to serve as laboratories in which the issue receives further study before it is addressed by this Court. *McCray v. New York*, 461 U.S. 961 (1983).
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> [T]here is no allegation in the petition for certiorari that there is a conflict between the decision of the Court of Appeals in this case and any other Federal Court of Appeals decision. Often the law develops in a more satisfactory fashion if this court withholds review of novel issues

> before differing views have been expressed by other federal courts. *Vasquez v. United States*, 454 U.S. 975 (1981).
>
> Petitions may have been denied because, even though serious constitutional questions were raised, it seemed to at least six members of the Court that the issue was either not ripe enough or too moribund for adjudication; that the question had better await the perspective of time or that time would soon bury the question or, for one reason or another, it was desirable to wait and see . . . *Darr v. Burfurd*, 339 U.S. 200 (1949).
>
> It may be desirable to have different aspects of an issue further illuminated by the lower courts. Wise adjudication has its own time for ripening. *Maryland v. Baltimore Radio Show*, 338 U.S. 912 (1949).

These judicial policy considerations militate in favor of a denial of certiorari in this case where there is no conflict among any of the decisions of lower federal and state courts regarding the same facts and question presented here.

Lynnbrook Farms, Murphy and *Brandt* involved essentially identical factual allegations and claims.[1] The plaintiffs alleged that their cattle suffered harm purportedly caused by vaccines manufactured by SBC. (Pet. App. at A-2; A-25; 898 F. Supp. at 813; 540 N.W.2d at 873) Plaintiffs contended that the vaccines either failed to protect against the diseases they were designed to counteract or were unsafe. (*Id.*) Plaintiffs asserted a variety of state law

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[1] In fact, counsel for Lynnbrook also represented the plaintiffs in *Murphy* and *Brandt*. The allegations contained in the Complaints in all three cases are virtually identical except for the names of the plaintiffs and the names of the vaccines at issue.

claims sounding in strict liability, negligence, misrepresentation, false advertising, and breach of implied warranties of merchantability and fitness. (Pet. App. at A-3; A-25; 898 F. Supp. at 813; 540 N.W.2d at 873) In all three cases, SBC submitted uncontroverted evidence that the vaccines at issue complied with APHIS' requirements for safety, efficacy, purity, potency and labeling. (Pet. App. at A-20; A-36; 540 N.W.2d at 875 n.3)

The courts in *Lynnbrook Farms, Murphy* and *Brandt* unanimously upheld the validity of APHIS' express declaration of preemption and found that each of the plaintiffs' claims fall within the scope of the declaration of preemption. (Pet. App. at A-20; A-36; 898 F. Supp. at 817-18; 540 N.W.2d at 878) The courts not only reached the same conclusions, they followed the same analysis and applied the same reasoning.[2]

First, each of the courts acknowledged the principle first announced by this Court in *United States v. Shimer*, 367 U.S. 374 (1961), and confirmed in *Fidelity Fed. Savings & Loan Ass'n v. de la Cuesta*, 458 U.S. 141 (1982), and *City of New York v. Federal Comm'n*, 486 U.S. 57 (1988), that a federal agency may expressly preempt state law even without express congressional authorization to do so. (Pet. App. at A-4 – A-6; A-28; 898 F. Supp. at 814-15; 540 N.W.2d at 874-76) To determine whether APHIS' declaration of preemption was valid, the courts applied the analysis set forth by this Court in *Shimer, Fidelity* and *City*

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[2] Lynnbrook's argument that this Court should exercise its supervisory powers because the Seventh Circuit purportedly departed from the accepted and usual course of judicial proceedings and sanctioned such a departure by a lower court, (Pet. App. 19-20), is of no moment because it is based solely upon (1) cases decided *before* both the August 27, 1992 declaration of preemption by APHIS and *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992); (2) cases in which the preemption defense was not asserted; and (3) cases in which the court wrote no opinion.

of New York. Accordingly, the courts asked: (1) whether the agency acted within the scope of its delegated authority; and (2) whether the agency clearly expressed its intent to preempt state law, including common law damages actions. (Pet. App. at A-6; A-29; 898 F. Supp. at 814-15; 540 N.W.2d at 874-76)

In concluding that APHIS acted within the scope of its delegated authority, each of the courts compared the authority delegated by Congress in VSTA to APHIS, to the language construed by this Court in *Shimer, Fidelity* and *City of New York* as empowering the agencies in those cases to preempt state law. The *Lynnbrook Farms, Murphy* and *Brandt* courts reasoned that the authority delegated to APHIS in the language of the statute and the legislative history was broad enough to permit APHIS to preempt state law. (Pet. App. at A-6 – A-13; A-29 – A-35; 898 F. Supp. at 814-15; 540 N.W.2d at 874-76)

As to APHIS' intent to preempt all state law, including common law damages actions, the *Lynnbrook Farms, Murphy* and *Brandt* courts reasoned that the agency used certain "magic" words – *i.e.*, stating its intent "to occupy the field" and its intent to preempt state "requirements different from or in addition to" those imposed by the agency – which dozens of courts have held preempt common law causes of action falling within the scope of the particular area of law preempted. (Pet. App. at A-13 – A-19; A-32 – A-35; 898 F. Supp. at 815-17; 540 N.W.2d at 876-78)

The district court in this case and the *Murphy* and *Brandt* courts did not have the benefit of reviewing the December 22, 1995 correspondence from Acting Administrator of APHIS, Terry L. Medley, to Senator Wellstone, which confirms the scope of APHIS' declaration of preemption. However, the Seventh Circuit stated that "although the case law supporting our conclusion is substantial, we are even more confident that APHIS intended to include common law damages actions within the scope of its preemption after reviewing the only official APHIS

statement (to our knowledge) explaining its intent in adopting the quoted regulation." (Pet. App. A-17) As set forth above, that correspondence confirmed that APHIS' intent was to preempt *all* state law whether "by statute, regulations *or other means.*" (Resp. App. A-29 – A-30) (Emphasis added.)

Having found that APHIS clearly expressed its intent to preempt state law, and having found that APHIS neither exceeded its statutory authority nor acted arbitrarily, capriciously or manifestly contrary to the statute, the *Lynnbrook Farms, Murphy* and *Brandt* courts applied the analysis set forth by this Court in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) to determine whether plaintiffs' claims fall within the scope of the declaration of preemption. (Pet. App. at A-20 – A-21; A-35 – A-37; 898 F. Supp. at 817-18; 540 N.W.2d at 878) In all three cases it was undisputed that APHIS had licensed each of the vaccines, and that through the licensure and post-licensure review processes, the agency necessarily determined that the vaccines satisfied all of its requirements. The courts unanimously held that each of the plaintiffs' claims, if accepted by a jury, would impose a requirement different from or in addition to APHIS' requirements regarding the safety, efficacy, purity, potency or labeling of the animal vaccines at issue. (*Id.*)

Because there is no conflict among the lower court decisions either in the analysis and reasoning they applied or the conclusions they reached, it would be unwise for this Court to address at this time the question presented by Lynnbrook. As in past cases, this Court should withhold review until the issue receives further study in lower courts where differing views may be expressed and illuminated.

II. There Is No Conflict With Relevant Decisions Of This Court.

Because the Seventh Circuit correctly applied the relevant decisions of this Court, Lynnbrook's petition for a Writ of Certiorari should be denied. As indicated above, the Seventh Circuit correctly applied the analysis set forth by this Court in *Shimer, Fidelity* and *City of New York* for determining the validity of APHIS' declaration of preemption. The Seventh Circuit also correctly applied the *Cipollone* analysis in determining that Lynnbrook's claims fall within the scope of APHIS' declaration of preemption.

In addition, the Seventh Circuit considered Lynnbrook's arguments that this Court's decision in *Lohr* requires a withdrawal of the Seventh Circuit's judgment and a reversal of the district court's judgment. Upon consideration of substantive arguments based upon *Lohr*, the Seventh Circuit correctly denied Lynnbrook's motion to recall mandate.

A. This Court in *Lohr* Explicitly Confirmed That The Term "Requirement" Contained In The MDA Preemption Clause Includes State Court Claims.

Lynnbrook's Argument IA, (Pet. App. at 8-12), is based upon its belief that this Court in *Lohr* held that the term "requirement" found in the MDA preemption clause does not encompass state common law damages actions. *This Court made no such holding*. Entirely to the contrary, five Justices *explicitly confirmed* this Court's holding in *Cipollone* that the term "requirements" *does* encompass state tort actions for damages. Speaking on behalf of herself, Chief Justice Rehnquist, and Justices Scalia and Thomas, Justice O'Connor concluded that 21 U.S.C. § 360k(a) preempts both state statutes and regulations *and* state common law actions falling within its scope:

> Whether relating to the labeling of cigarettes or the manufacture of medical devices, state common-law damages actions operate to require manufacturers to comply with common-law duties. *As Cipollone declared, in answer to the same argument raised here that common-law actions do not impose requirements, "such an analysis is at odds both with the plain words" of the statute and "with the general understanding of common-law damages actions."* [Citation omitted.] *If § 360k's language is given its ordinary meaning, it clearly pre-empts any state common-law action that would impose a requirement different from, or in addition to, that applicable under the FDCA – just as it would pre-empt a state statute or regulation that had that effect. Justice BREYER reaches the same conclusion.*

116 S. Ct. at 2262-63 (emphasis added). In his concurring opinion, Justice Breyer expressly agreed:

> . . . [T]he MDA will sometimes pre-empt a state-law tort suit. I basically agree with Justice O'CONNOR's discussion of this point and with her conclusion. [Citation omitted.] The statute's language, read literally, supports that conclusion. . . . *One can reasonably read the word "requirement" as including the legal requirements that grow out of the application, in particular circumstances, of a State's tort law.*
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> * * *
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> Consequently, I believe that ordinarily, *insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action.* It is possible that the plurality also agrees on this point, although it does not say so explicitly.

116 S. Ct. at 2259 (emphasis added). Thus, *Lohr* confirms that this Court continues to hold that the term "requirements" *includes* state tort claims.[3]

Moreover, in light of the weight accorded by the majority in *Lohr* to the FDA's preemptive intent, APHIS' express confirmation that the decisions of the district court in this case and the courts in *Murphy* and *Brandt* correctly reflect the scope of its preemptive intent is highly significant. In *Lohr*, the Supreme Court was confronted, in net effect, with *two* different preemption clauses – 21 U.S.C. § 360k(a),[4] authored by Congress, and 21 C.F.R. § 808.1(d),[5] authored by the FDA. In giving

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[3] Lynnbrook's argument that the word "requirement" in the MDA preemption clause does not encompass state tort claims stems from language contained in Part IV of Justice Stevens' plurality opinion. Lynnbrook ignores the fact that Justice Breyer expressly *declined* to join Part IV of Justice Stevens' opinion. *See* 116 S. Ct. at 2261-62. With few exceptions, Lynnbrook's citations to *Lohr* in its petition are taken from Part IV of Justice Stevens' opinion. (Pet. at 9, 10, 11, 12, 13, 14, 15.) Because only four Justices subscribed to Part IV of the plurality opinion, Lynnbrook is repeatedly mistaken in arguing that the expressions of Justice Stevens found in Part IV represent this Court's official holding.

[4] 21 U.S.C. § 360k(a) provides in pertinent part:

> No State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under [the MDA] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in the requirement applicable to the device under [the MDA].

[5] 21 C.F.R. § 808.1(d) provides in pertinent part:

> State or local requirements are preempted only when the Food and Drug Administration has established

controlling weight to the *FDA's interpretation* of 21 U.S.C. § 360k(a) and *not* the plain language of the statute itself, Justices Stevens and Breyer both emphasized the FDA's administrative expertise and informed judgment to ascertain the proper effect of its regulations upon state law. As Justice Stevens stated:

> Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the [MDA], *the agency is uniquely qualified to determine whether a particular form of state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," Hines v. Davidowitz*, 312 U.S. 52, 67 (1941), *and therefore, whether it should be pre-empted*. For example, Congress explicitly delegated to the FDA the authority to exempt state regulations from the pre-emptive effect of the MDA – *an authority that necessarily*

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specific counterpart regulations or there are other specific requirements applicable to a particular device under the [MDA], thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements. There are other State or local requirements that affect devices that are not preempted by [21 U.S.C. § 360k(a)] because they are not "requirements applicable to a device" within the meaning of [21 U.S.C. § 360k(a)]. The following are examples of State or local requirements that are not regarded as preempted by [21 U.S.C. § 360k(a)]:

(1) *Section [360k(a)] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices* (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices. (Emphasis added.)

> *requires the FDA to assess the pre-emptive effect that the act and its own regulations will have on state laws. See* § 360k(b). . . . *The ambiguity in the statute – and the Congressional grant of authority to the agency on the matter contained within – provide a "sound basis" . . . for giving substantial weight to the agency's view of the statute.* See *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984); *Hillsborough Cty. [v. Automated Medical Laboratories, Inc.]*, 471 U.S. [707] at 714 (considering FDA understanding of pre-emptive effect of its regulations "dispositive").

116 S. Ct. at 2255-56 (emphasis added). Justice Breyer agreed:

> [T]his court has previously suggested that, in the absence of a clear Congressional demand as to preemption, *courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect.* See *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 721 (1985); cf. *Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. ___, ___ (1996) (*slip op.*, at 3-5); *Lawrence County v. Lead-Deadwood School Dist. No. 40-1*, 469 U.S. 256, 261-262 (1985); *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-845 (1984). To draw a similar inference here makes sense, and not simply because of the statutory ambiguity. *The [FDA] is fully responsible for administering the MDA. [Citation omitted.] That responsibility means informed agency involvement and, therefore, special understanding of the likely impact of both state and federal requirements, as well as an understanding of whether (or the extent to which) state requirements may interfere with federal objectives. See Hillsborough*, 471 U.S. at 721. The FDA can translate these understandings into

> particularized pre-emptive intentions accompanying its various rules and regulations. See *id.*, at 718.
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> * * *
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> *It therefore seems to me that the better indicator of the FDA's intent is its pre-emption-related regulation. And that regulation's word "specific" would seem a reasonable exercise of the leeway that statutory language and practical administrative circumstance suggest Congress intended to grant to the agency.*

116 S. Ct. at 2260 (emphasis added).

Read properly, *Lohr* vividly illustrates the degree of deference to be given to a federal agency's authorized declaration of preemption. So long as a federal agency acts within the scope of the authority granted to it by Congress,[6] the agency's expressed preemptive intent will prevail even over ambiguous Congressional declarations falling within the same area, in light of the agency's superior "informed involvement" and "special understanding" of the impact of its preemptive intent upon state law.

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[6] On pages 17-18 of its petition, Lynnbrook offers a new argument – that APHIS' declaration of preemption is manifestly contrary to 21 U.S.C. § 151, and therefore, is beyond the scope of authority granted to APHIS by Congress. Having never before asserted this argument, Lynnbrook has waived it. Furthermore, this argument is completely unrelated to this Court's holding in *Lohr*. Finally, the argument is incorrect. Congress delegated to APHIS the authority to determine which vaccines are not "worthless, contaminated, dangerous or harmful." APHIS has specified that vaccines which satisfy its standards for safety, efficacy, potency, purity and labeling are *not* "worthless, contaminated, dangerous or harmful." That declaration is entitled to controlling weight by this Court. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 845 (1984).

As the Seventh Circuit correctly noted, when APHIS issued its declaration of preemption in August, 1992, APHIS patterned its language after other Congressional declarations of preemption, which according to this Court in *Cipollone*, had the effect of preempting *both* state positive enactments *and* state tort actions falling within their scope. More importantly, APHIS' December 22, 1995 correspondence confirms the agency's intent to preempt *all* state law, including the claims at issue in *Brandt, Murphy*, and this case, which sought to impose requirements different from or in addition to those imposed by APHIS regarding the safety, efficacy, purity, potency and labeling of the vaccines at issue.

Thus, the Seventh Circuit followed the command of *Lohr*, to the letter: it correctly construed APHIS' use of the term "requirements" in its declaration of preemption as encompassing state tort actions; it correctly ascertained the scope of APHIS' preemptive intent, as manifested by its declaration of preemption and its December 22, 1995 correspondence to Senator Wellstone; it afforded controlling weight to APHIS' expressed preemptive intent; and, it examined the claims asserted by Lynnbrook to determine whether or not they fall within the area intended by APHIS to be preempted. The fact that the FDA intended a *different* preemptive effect for claims arising under the MDA's preemption clause, as illustrated by 21 C.F.R. § 808.1(d), is of no moment.

B. Significant Policy Differences Between VSTA And The MDA Explain Why APHIS Intends A Broader Preemptive Effect Than That Provided By The FDA For The MDA.

Lynnbrook's argument that the MDA and VSTA serve similar purposes and therefore, the Seventh Circuit's decision conflicts with this Court's decision in *Lohr*, (Pet. App. at 13-15), fails for a number of reasons. First, this argument is based upon Part IV of the Opinion which did

not command a majority of the Justices. Second, an analysis of the purpose and history of the statute is unnecessary where, as here, APHIS unambiguously expressed its intent to preempt all state law including common law damages actions. Nonetheless, even if such an analysis is undertaken, VSTA warrants and APHIS intends a broader preemptive effect than that provided by the FDA for the MDA.

The likely reason why APHIS intends a broader preemptive effect than that provided by the FDA in 21 C.F.R. § 808.1(d) can be found in the different missions of the two agencies, the different statutes they must implement, and fundamental differences in the products and industries they regulate. Animal vaccines, for instance, promote the health of animals which produce food for all Americans – *e.g.*, dairy cattle (milk, butter, cheese and beef), beef cattle (meat), poultry (meat and eggs), and swine (meat). When used, animal vaccines can substantially enhance the health of these animals, to the benefit of not just the individual animal owner, but the quantity, quality, and affordability of the nation's food supply.

Encouraging animal producers to *use* these vaccines is an important part of APHIS' mission. As the legislative history to the 1985 amendments to the VSTA indicates, Congress sought to promote not just the safety and efficacy of animal vaccines, but also their *availability* via national, uniform standards and the elimination of burdens upon commerce. APHIS could reasonably conclude, based upon its expertise and knowledge of the market, that imposing tort liability upon manufacturers of animal vaccines which have fully satisfied all of APHIS' standards: (1) does little to further enhance the safety and efficacy of animal vaccines which have already undergone APHIS' thorough pre-licensure approval process; (2) subjects vaccine manufacturers to additional burdens and costs, causing vaccine prices to increase and even forcing some manufacturers out of business altogether; and, (3) diminishes animal producers' incentive to use animal

vaccines (since agriculture prices are determined by national markets and bear no relation to an individual farmer's cost of production, which in turn renders animal producers unable to recover their increased vaccine costs) – thereby threatening the quality, quantity and affordability of the nation's food supply.

By contrast, the FDA's mission with respect to human medical devices is quite different. As the Supreme Court noted in *Lohr*, most medical devices sold in this country are so-called "substantial equivalent" devices permitted by § 510(k) of the MDA which, unlike animal vaccines, undergo little agency scrutiny. 116 S. Ct. at 2247-49. Furthermore, the FDA has *not* been charged by Congress with eliminating and minimizing burdens upon commerce in order to insure that medical devices are available at a reasonable cost to consumers. Users of medical devices are typically driven in their decision-making not by the cost of the device, but by their personal health needs and the availability of health insurance, private or public. Finally, the benefits of medical devices are essentially confined to the health of the specific individuals for whom they are prescribed; a consumer's choice to use or not use a given medical device carries few if any implications for society as a whole. Because substantial policy differences exist between the purposes of VSTA and the MDA, there is no conflict between this Court's decision in *Lohr* and the Seventh Circuit's decision in this case.

C. *Lohr* Cannot Resurrect Any Claims Lynnbrook Waived For Noncompliance With Federal Standards.

Lynnbrook's attempt to resurrect a belated claim for noncompliance with federal standards based upon this Court's holding in *Lohr* must fail. (*See* Pet. App. 15-17) SBC agrees that the question of compliance with APHIS standards has always been a material fact in this case and an essential part of SBC's preemption defense. The uncontroverted evidence accompanying SBC's motion for

summary judgment demonstrates that its vaccines *did* satisfy all applicable federal requirements. To demonstrate that Lynnbrook's claims were ones which, if accepted by a jury, would impose "different or additional" requirements, SBC adduced the material fact that SBC's vaccines fully complied with all applicable APHIS standards. With that fact established, the only way a jury could find the vaccines to be unsafe, inefficacious or improperly labeled – the essential allegations of the Amended Complaint – was by imposing standards "different from or in addition to" APHIS' requirements.

To establish this fact, SBC submitted in support of its motion for summary judgment the Affidavit of Cyril G. Gay, D.V.M., Ph.D., which in pertinent part provided:

> Each of the SBC vaccines involved in this litigation, through the licensure process and through post-licensure testing and evaluation, has been determined by APHIS to satisfy all requirements for purity, safety, potency and efficacy contained in the APHIS standards. Each has been designed, manufactured and tested pursuant to APHIS standards, and of necessity APHIS approved the content and sufficiency of all design, manufacturing and testing data submitted prior to licensure of each vaccine. In addition, the text, layout and design of all labeling on these vaccines, including the packaging and product inserts, have been specifically approved in writing by APHIS.

(Resp. App. at A-17 – A-24)[7]

Lynnbrook, of course, could have opposed SBC's motion for summary judgment on the grounds that material facts were at issue, *i.e.*, that evidence existed showing

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[7] Lynnbrook failed to disclose to this Court that SBC submitted uncontroverted evidence of compliance with APHIS standards through the testimony of Dr. Gay.

that the vaccines somehow did not meet APHIS' standards. To do that, appellant was obligated to introduce affirmative evidence negating the facts recited in Dr. Gay's Affidavit. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Mitchell v. Collagen Corp.*, 67 F.3d 1268, 1282-83 (7th Cir. 1995); *see also* Rule 2.9 of the General Rules of the United States District Court for the Central District of Illinois.

Lynnbrook did not do so.[8] No "Statement of Genuine Issues" setting forth any disputed facts appeared in Lynnbrook's brief in opposition to SBC's motion for summary judgment. Lynnbrook neither submitted any affidavits or other evidence in opposition to SBC's motion for summary judgment, nor availed itself of Rule 56(f) of the Federal Rules of Civil Procedure to take discovery on any material factual issue. To the contrary, appellant stipulated below that *no* discovery was required to adjudicate the preemption issue. (Resp. App. A-26 – A-28) Furthermore, Lynnbrook argued both before the district court and the Seventh Circuit that compliance with APHIS' requirements was neither dispositive nor a defense to liability because the requirements were intended only to be "minimum standards." Finally, Lynnbrook's counsel

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[8] Notably, the primary vaccine at issue in this case – *CattleMaster 4 – was also the primary vaccine involved in *Brandt*. Counsel for Lynnbrook in this case also represented the plaintiffs in *Brandt*. Unlike this case, the preemption motion in *Brandt* was not brought until essentially all discovery was completed. Yet, as the Minnesota Court of Appeals observed in *Brandt*, there was no evidence, nor even any claim, in that case that the *CattleMaster 4 vaccine failed to comply with applicable APHIS standards. 540 N.W.2d at 875, n. 3. Thus, it is hardly surprising that Lynnbrook has never claimed, until this Court's decision in *Lohr*, that SBC's vaccines failed to meet APHIS' standards.

conceded during oral argument before the Seventh Circuit that, if the Court were to find that APHIS' declaration covered state tort claims, all of the counts of the Amended Complaint would be preempted – *i.e.*, that Lynnbrook's claims sought to establish requirements "different from or in addition to" those imposed by APHIS regarding the safety, efficacy, purity, potency and labeling of SBC's vaccines.

To summarize, there has never been, and is not now, any issue in this case that SBC's vaccines somehow failed to comply with APHIS' licensing requirements. Dr. Gay's uncontroverted Affidavit conclusively establishes that SBC's vaccines satisfied all of APHIS' requirements. This case never has been, and cannot be, one for noncompliance with APHIS' regulatory standards. Although Lynnbrook attempted to resurrect this argument at the Seventh Circuit following this Court's decision in *Lohr*, the Seventh Circuit observed that "it is undisputed the SBC manufactured and marketed *CattleMaster 4 and Ultrabac 7/Somubac according to all APHIS regulations. This is not a case involving non-compliance." (Pet. App. at A-20)

Lohr in no way calls this portion of the Seventh Circuit's holding in question. Even before *Lohr*, APHIS stated that it did not intend to preempt state tort actions arising from non-compliance with APHIS' regulatory standards. (Resp. App. at A-29) Thus, *Lohr* adds nothing new to the debate.

Because the Seventh Circuit's decision is consistent with the relevant decisions of this Court, Lynnbrook's petition should be denied. This Court should not remand the case to the Seventh Circuit to be reconsidered in light of *Lohr*, because as indicated above, the parties briefed all of the substantive arguments based upon *Lohr* to the Seventh Circuit when Lynnbrook asked the court to recall mandate. The Seventh Circuit considered those arguments and denied the motion. (Resp. App. at A-31) Finally, the application of *Lohr* to APHIS' declaration of

preemption is not a question this Court should decide at this time. The Seventh Circuit is the *only* court to have considered this issue. Allowing other courts to consider the question presented by this case in light of *Lohr* could lead to the expression of differing views and a conflict which does not exist at this time. Given this Court's limited judicial resources, it would make better sense to decide this question after the issue has had a chance to ripen. Accordingly, this Court should summarily deny Lynnbrook's petition for a Writ of Certiorari.

CONCLUSION

For the reasons stated above, the petition for a Writ of Certiorari should be denied.

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF ILLINOIS
PEORIA DIVISION

LYNNBROOK FARMS, an Illinois General Partnership, Plaintiff, vs. SMITHKLINE BEECHAM CORPORATION, and NORDEN LABORATORIES, INC., Defendants.	CASE NO. 94-CV-1227 AMENDED COMPLAINT and DEMAND FOR JURY TRIAL

Plaintiff, LYNNBROOK FARMS, for its cause of action, alleges as follows:

GENERAL ALLEGATIONS

1. Plaintiff, LYNNBROOK FARMS, located at Williamsfield, Knox County, Illinois, is a General Partnership organized under the laws of the State of Illinois, and its partners are as follows, to-wit: Lester Brooks Potts, Jr., who resides at Williamsfield, Knox County, Illinois; Robert Lynn Potts, who resides at Dahinda, Knox County, Illinois; Mary Diane Potts, who resides at Williamsfield, Knox County, Illinois; and Gayla Marie Potts, who resides at Dahinda, Knox County, Illinois.

2. Defendant, SMITHKLINE BEECHAM CORPORATION, is and was at all times material hereto a corporation incorporated under the laws of the State of

Pennsylvania having its principal place of business in a State other than the State of Illinois.

3. Defendant, NORDEN LABORATORIES, INC., was at all times material hereto a corporation incorporated under the laws of the State of Delaware having its principal place of business in a State other than the State of Illinois.

4. The matter in controversy exceeds, exclusive of interest and costs, the sum of Fifty Thousand Dollars ($50,000.00).

5. At all relevant times, Plaintiff was engaged in the business of raising and selling cattle.

6. Defendant, SMITHKLINE BEECHAM CORPORATION, is and was at all times material hereto a corporation duly authorized to transact business in the State of Illinois.

7. Defendant, SMITHKLINE BEECHAMN CORPORATION, a Pennsylvania Corporation, may have become the successor in interest to Defendant, NORDEN LABORATORIES, INC., including the claims set out herein, as the result of a 1990 joint venture with Defendant, NORDEN LABORATORIES, INC.

8. Defendant, SMITHKLINE BEECHAM CORPORATION, a Pennsylvania Corporation, may have become the successor in interest to Defendant, NORDEN LABORATORIES, INC., including the claims set out herein, as the result of a 1992 merger with Defendant, NORDEN LABORATORIES, INC.

9. SMITHKLINE BEECHAM CORPORATION and NORDEN LABORATORIES, INC. are hereinafter collectively referred to as "Defendants".

COUNT I – STRICT LIABILITY

10. Plaintiff incorporates into this Count I all the allegations of paragraphs 1 through 9 of its General Allegations as though fully set forth herein.

11. At all times material hereto, the Defendants were engaged in the business of manufacturing a variety of animal vaccines which were sold in the State of Illinois to various persons and firms for distribution to the general public, as ultimate consumers, and promoted by sales representatives in the State of Illinois.

12. Among the animal vaccines formulated, compounded, manufactured, tested, marketed and recommended by Defendants for use with cattle is their product known as "*CattleMaster4".

13. While engaged in the manufacture and sale of animal vaccines, the Defendants sold *CattleMaster4 vaccine to, among others, The Miller Company, Inc., located in Morton, Tazewell County, Illinois.

14. Defendants expected the vaccine sold to The Miller Company to reach consumers in the condition in which it was sold.

15. During or about May, 1992, Plaintiff purchased from The Miller Company the vaccine, *CattleMaster4, which is the product of Defendants for vaccination of its cattle. The objective of the vaccinations was to aid in the prevention of debilitating or mortal infections and diseases.

16. During or about May, 1992, the said vaccine was shipped refrigerated to Plaintiff via United Parcel Service.

17. The vaccine, *CattleMaster4, was kept refrigerated upon receipt by Plaintiff.

18. During or about June, 1992, Plaintiff vaccinated its cattle with the aforesaid vaccine which was in the same condition in which it was supplied to Plaintiff and The Miller Company.

19. At the time of vaccinating its cattle with Defendants' product, Plaintiff used the vaccine in accordance with the instructions and according to the appropriate business custom.

20. Plaintiff, at the time of the aforesaid use of *CattleMaster4, intended the vaccine to aid in the prevention of bovine viral diarrhea, bovine respiratory syncytial virus, infectious rhinotracheitis virus, and parainfluenza in healthy animals, and was unaware of any defect or dangerous condition in the vaccine and expected the vaccine to be safe for use in a foreseeable manner.

21. Notwithstanding the inoculation of Plaintiff's cattle with the Defendants' product, Plaintiff's cattle, after the said injections of mid 1992 were administered, contracted debilitating and mortal infections and diseases which killed certain of Plaintiff's animals or so debilitated certain others as to make it necessary for Plaintiff to sell or dispose of them at a loss.

WHEREFORE, Plaintiff PRAYS for a Judgment jointly and severally against Defendants on Count I for an amount in excess of $50,000, plus interest thereon at the

highest legal rate, plus punitive damages, plus reasonable attorneys fees, plus the costs of this action.

PLAINTIFF DEMANDS A TRIAL BY JURY UNDER FED. R. CIV. P. 38.

COUNT II – BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE UNDER THE ILLINOIS UNIFORM COMMERCIAL CODE (810 ILCS 5/1-101 ET SEQ.)

22. Plaintiff incorporates into this Count II all the allegations of paragraphs 1 through 21 of its General Allegations and its First Count as though fully set forth herein.

23. By the sale of the vaccine known as *CattleMaster4, the Defendants impliedly warranted, within the meaning of the Illinois Uniform Commercial Code, 810 ILCS 5/1-101 et seq., that such vaccine was fit and suitable for the purposes for which it was manufactured and that it was safe when used in a foreseeable manner for inoculating cattle to aid in preventing bovine viral diarrhea, bovine respiratory syncytial virus, infectious rhinotracheitis virus, and parainfluenza in healthy cattle.

24. At the time of contracting to sell said vaccine to Plaintiff, Defendants had reason to know of the particular purpose for which Plaintiff required said vaccine, specifically, to prevent bovine viral diarrhea, bovine respiratory syncytial virus, infectious rhinotracheitis virus, and parainfluenza in healthy cattle.

25. In purchasing and using the vaccine, Plaintiff relied on Defendants and their expertise and judgment in

the area of manufacturing and marketing animal vaccines.

26. The vaccine was not fit for the purpose intended in that it did not aid in preventing bovine viral diarrhea, bovine respiratory syncytial virus, infectious rhinotracheitis virus, and parainfluenza in healthy cattle.

27. As a proximate result of the Defendants' breach of warranty of fitness for a particular purpose, Plaintiff sustained damages in the manner previously alleged.

WHEREFORE, Plaintiff PRAYS for a Judgment jointly and severally against Defendants on Count II for an amount in excess of $50,000, plus interest thereon at the highest legal rate, plus punitive damages, plus reasonable attorneys fees, plus the costs of this action.

PLAINTIFF DEMANDS A TRIAL BY JURY UNDER FED. R. CIV. P. 38.

COUNT III – BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY UNDER THE ILLINOIS UNIFORM COMMERCIAL CODE (810 ILCS 5/1-101, ET SEQ.)

28. Plaintiff incorporates into this Count III the allegations of paragraphs 1 through 27 of the General Allegations and the First and Second Counts as though fully set forth herein.

29. Defendants, through their agents, possessed special knowledge, skill and expertise concerning the formulation, compounding, testing, manufacturing, labeling, marketing, selection and use of medications and vaccines for animals, including cattle of the kind produced by Plaintiff, and were therefore "merchants" for

purposes of the Illinois Uniform Commercial Code, 810 ILCS 5/1-101 et seq.

30. Defendants impliedly warranted that their *CattleMaster4 product was of merchantable quality with respect to goods of their kind in that they would pass without objection in the trade, aid in the prevention of debilitating or moral infections and diseases, and provide an effective, safe, viable and successful inoculate.

31. The vaccine failed to protect Plaintiff's cattle from debilitating or mortal infections and diseases, including bovine viral diarrhea, bovine respiratory syncytial virus, infectious rhinotracheitis virus, and parainfluenza.

32. As a consequence of the failure of *CattleMaster4 to prevent the foregoing diseases, said vaccine was unfit for its ordinary purpose and would not pass without objection in the trade, and was thus unmerchantable at the time of sale.

33. As a direct, proximate result of the breach of the implied warranty or warranties by Defendants with respect to their product, Plaintiff has sustained damages as previously alleged.

WHEREFORE, Plaintiff PRAYS for Judgment jointly and severally against Defendants on Count III of its Complaint for an amount in excess of $50,000, plus interest thereon at the highest legal rate, plus punitive damages, plus attorneys fees, plus costs of this action.

PLAINTIFF DEMANDS A TRIAL BY JURY UNDER FED. R. CIV. P. 38.

COUNT IV – FRAUDULENT MISREPRESENTATION

34. Plaintiff incorporates into this Count IV the allegations of paragraphs 1 through 33 of the General Allegations and the First, Second and Third Counts as though fully set forth herein.

35. Defendants, acting through their officers, agents, servants, representatives, or employees, supplied false information through advertising and promotion of the *CattleMaster4 vaccine by stating and claiming that said vaccine was effective and safe when used in a foreseeable manner.

36. Said representations were made as a statement of fact and were false when made.

37. Said representations were made by Defendants and their agents with knowledge of their falsity or with reckless disregard for the truth thereof and a willful and wanton disregard for the truth and the rights of the Plaintiff.

38. Defendants made said representations with the intention of inducing Plaintiff to act upon said statements.

39. In reliance on the truth of such misrepresentations, Plaintiff purchased *CattleMaster4 from The Miller Company and used the same in the manner and for the purpose as advertised and promoted by Defendants.

40. As a proximate result of Plaintiff's reliance upon Defendants' statements, Plaintiff has sustained damages in the manner previously alleged.

WHEREFORE, Plaintiff PRAYS for Judgment jointly and severally against Defendants on Count IV of its Complaint for an amount in excess of $50,000, plus interest thereon at the highest legal rate, plus punitive damages, plus reasonable attorneys fees, plus the costs of this action.

PLAINTIFF DEMANDS A TRIAL BY JURY UNDER FED. R. CIV. P. 38.

COUNT V – ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT (815 ILCS 505/1 ET SEQ.)

41. Plaintiff incorporates into this Count V the allegations of paragraphs 1 through 40 of the General Allegations and the First, Second, Third and Fourth Counts as though fully set forth herein.

42. At all times material hereto, Plaintiff was a "person" for purposes of the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1 et seq.

43. At all times material hereto, Plaintiff was a "consumer" for purposes of the Illinois Consumer Fraud and Deceptive Business Practices Act.

44. At all times material hereto, Defendants were engaged in "trade" or "commerce" for purposes of the Illinois Consumer Fraud and Deceptive Business Practices Act.

45. In violation of Section 2 of the Illinois Consumer Fraud and Deceptive Business Practices Act, Defendants, acting through their officers, agents, employees, servants, or representatives, employed deception, fraud, false pretense, false promise, misrepresentation, and concealment,

suppression, or omission of material fact in that they supplied false information through their advertising and promotion of the *CattleMaster4 vaccine by stating and claiming that said vaccine was effective and safe when used in a foreseeable manner.

46. Said representations were made as statements of material fact and were false when made.

47. Said representations were made by Defendants and their agents with knowledge of their falsity or with reckless disregard for the truth thereof and a willful and wanton disregard for the truth and the rights of the Plaintiff.

48. Defendants made said representations with the intention of inducing Plaintiff to act upon said statements.

49. In reasonable reliance on the truth of such misrepresentations, Plaintiff purchased *CattleMaster4 from The Miller Company and used the same in the manner and for the purpose as advertised and promoted by Defendants.

50. As a proximate result of Plaintiff's reliance upon Defendants' statements, Plaintiff was damaged in the manner previously alleged.

WHEREFORE, Plaintiff PRAYS for Judgment jointly and severally against Defendants on Count V of its Complaint for an amount in excess of $50,000, plus interest thereon at the highest legal rate, plus punitive damages, plus reasonable attorneys fees, plus the costs of this action.

PLAINTIFF DEMANDS A TRIAL BY JURY UNDER FED. R. CIV. P. 38.

COUNT VI – FAILURE TO WARN (STRICT LIABILITY)

51. Plaintiff incorporates into this Count VI the allegations of paragraphs 1 through 50 of the General Allegations and the First, Second, Third, Fourth and Fifth Counts as though fully set forth herein.

52. The *CattleMaster4 vaccine sold to Plaintiff by Defendants was unreasonably dangerous and in a defective condition because the said vaccine was not accompanied by an adequate warning that would have allowed Plaintiff to use the product without injury to its cattle. The warning accompanying the product was inadequate in that it failed to advise Plaintiff that use of said product in conjunction with other products could cause a dangerous immunosuppressive reaction in the cattle, resulting in the illness and/or death of the cattle.

53. As a result of the defective and unreasonably dangerous condition of the *CattleMaster4 vaccine, Plaintiff incurred damage in the manner previously alleged.

WHEREFORE, Plaintiff PRAYS for Judgment jointly and severally against Defendants on Count VI of its Complaint for an amount in excess of $50,000, plus interest thereon at the highest legal rate, plus punitive damages, plus reasonable attorneys fees, plus the costs of this action.

PLAINTIFF DEMANDS A TRIAL BY JURY UNDER FED. R. CIV. P. 38.

COUNT VII – STRICT LIABILITY

54. Plaintiff incorporates into this Count VII the allegations of paragraphs 1 through 53 of the General Allegations and the First, Second, Third, Fourth, Fifth and Sixth Counts as though fully set forth herein.

55. At all times material hereto, the Defendant, SMITHKLINE BEECHAM CORPORATION, was engaged in the business of manufacturing a variety of animal vaccines which were sold in the State of Illinois to various persons and firms for distribution to the general public, as ultimate consumers, and promoted by sales representatives in the State of Illinois.

56. Among the animal vaccines formulated, compounded, manufactured, tested, marketed and recommended by Defendant, SMITHKLINE BEECHAM CORPORATION, for use with cattle is its product known as Ultrabac7/Somubac.

57. While engaged in the manufacture and sale of animal vaccines, the Defendant, SMITHKLINE BEECHAM CORPORAITON, sold Ultrabac7/Somubac vaccine to, among others, The Miller Company, Inc., located in Morton, Tazewell County, Illinois.

58. Defendant, SMITHKLINE BEECHAM CORPORATION, expected the said vaccine sold to The Miller Company to reach consumers in the condition in which it was sold.

59. During or about May, 1992, Plaintiff purchased Ultrabac7/Somubac, which is the product of the Defendant, for vaccination of its cattle. The objective of the

vaccinations was to aid in the prevention of debilitating or mortal infections and diseases.

60. During or about May, 1992, the vaccine, Ultrabac7/Somubac, was shipped refrigerated to Plaintiff via United Parcel Service.

61. The said vaccine, Ultrabac7/Somubac, was kept refrigerated upon receipt by Plaintiff.

62. During or about June, 1992, Plaintiff vaccinated its cattle with the aforesaid vaccine which was in the same condition in which it was supplied to Plaintiff and The Miller Company by Defendant, SMITHKLINE BEECHAM CORPORATION.

63. At the time of vaccinating its cattle with the product of the Defendant, SMITHKLINE BEECHAM CORPORATION, Plaintiff used the vaccine in accordance with the instructions and according to the appropriate business custom.

64. At the time of the aforesaid use of the Ultrabac7/Somubac vaccine, Plaintiff intended the said vaccine to aid in the prevention of Haemophilus somnus related infections and other mortal and dangerous diseases in healthy animals, and was unaware of any defect or dangerous condition in the vaccine and expected the vaccine to be safe for use in a foreseeable manner.

65. Notwithstanding the inoculation of Plaintiff's cattle with the product of the Defendant, SMITHKLINE BEECHAM CORPORATION, Plaintiff's cattle, after the injections of mid 1992 were administered, contracted debilitating and mortal infections and diseases which

killed certain of Plaintiff's animals or so debilitated certain others as to make it necessary for Plaintiff to sell or dispose of them at a loss.

WHEREFORE, Plaintiff PRAYS for a Judgment against Defendant, SMITHKLINE BEECHAM CORPORATION, on Count VII for an amount in excess of $50,000, plus interest thereon at the highest legal rate, plus punitive damages, plus reasonable attorneys fees, plus the costs of this action.

PLAINTIFF DEMANDS A TRIAL BY JURY UNDER FED. R. CIV. P. 38.

COUNT VIII – FAILURE TO WARN "STRICT LIABILITY"

66. Plaintiff incorporates into this Count VIII the allegations of paragraphs 1 through 65 of the General Allegations and the First, Second, Third, Fourth, Fifth, Sixth and Seventh Counts as though fully set forth herein.

67. The Ultrabac7/Somubac vaccine sold to Plaintiff by Defendant, SMITHKLINE BEECHAM CORPORATION, was unreasonably dangerous and in a defective condition because it was not accompanied by an adequate warning that would have allowed Plaintiff to use the product without injury to its cattle. The warning accompanying the product was inadequate in that it failed to advise Plaintiff that the use of said product in conjunction with other products could cause a dangerous immunosuppressive reaction in the cattle resulting in the illness and/or death of the cattle.

68. As a result of the defective and unreasonably dangerous condition of the Ultrabac7/Somubac vaccine,

Plaintiff incurred damage in the manner previously alleged.

WHEREFORE, Plaintiff PRAYS for a Judgment against Defendant, SMITHKLINE BEECHAM CORPORATION, on Count VIII of the Complaint for an amount in excess of $50,000, plus interest thereon at the highest legal rate, plus punitive damages, plus reasonable attorneys fees, plus the costs of this action.

PLAINTIFF DEMANDS A TRIAL BY JURY UNDER FED. R. CIV. P. 38.

LYNNBROOK FARMS, an Illinois General partnership

By: /s/ Matthew C. Potts
Matthew C. Potts

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/lit/lynnbr.lit

CERTIFICATE OF SERVICE

I, Matthew C. Potts, an Attorney for Plaintiff, hereby Certify under penalties as provided by law, that I served the foregoing Amended Complaint upon the Registered Agent for the Defendants therein by enclosing two (2) copies of the same in an envelope plainly addressed as follows:

SMITHKLINE BEECHAM CORPORATION and
NORDEN LABORATORIES, INC. a/k/a
SMITHKLINE BEECHAM CORPORATION
c/o CT CORPORATION
208 South LaSalle Street
Chicago, IL 60604

and by depositing said envelope with first-class postage fully prepaid in a United States mailbox at Elmwood, Illinois, on this 3rd day of June, 1994.

/s/ Matthew C. Potts
Matthew C. Potts

IN THE UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF ILLINOIS
PEORIA DIVISION

LYNNBROOK FARMS, an Illinois General Partnership,	)	
Plaintiff,	)	Case No. 94-CV-1227
v.	)	
SMITHKLINE BEECHAM CORPORATION, and NORDEN LABORATORIES, INC.,	)	
Defendants.	)	

AFFIDAVIT OF CYRIL G. GAY, D.V.M., Ph.D.

STATE OF NEBRASKA)
) SS.
COUNTY OF LANCASTER)

Cyril G. Gay, D.V.M., Ph.D., being duly sworn upon his oath, deposes and states as follows:

1. I am an adult witness legally competent to testify in this matter as to the items set forth below, which are based upon my personal knowledge and my review of certain business records maintained by SmithKline Beecham Animal Health, an unincorporated division of SmithKline Beecham Corporation ("SBC").

2. I am currently employed by SBC as its Associate Director, Biological Regulatory Affairs, Worldwide. In that capacity, I am familiar with the licenses obtained by SBC from the Animal and Plant Health Inspection Service

("APHIS") of the United States Department of Agriculture ("USDA") for the animal vaccines involved in this litigation. I am also familiar with the regulations promulgated and enforced by APHIS governing the design, manufacture, distribution, testing and labelling of animal vaccines.

3. APHIS' mandate is to ensure that all animal vaccines prepared and marketed in the United States are *pure, safe, potent,* and *efficacious.* 9 C.F.R. § 113.5(a) (1994). To ensure that these goals are satisfied. APHIS has established a complex regulatory program governing the design, manufacture, distribution, testing, and labelling of animal vaccines. *See* 9 C.F.R. §§ 101-124 (1994). Under both VSTA and the regulations promulgated thereunder, establishments at which animal vaccines are manufactured must be licensed by APHIS. 21 U.S.C.A. §§ 151, 154 (West Supp. 1994); 9 C.F.R. § 102.2 (1994). In addition, every animal vaccine manufactured and distributed in the United States must be licensed by APHIS before it may be marketed. 21 U.S.C.A. § 151 (West Supp. 1994); 9 C.F.R. § 102.1 (1994).

4. The first step in the process for a manufacturer seeking licensure of an animal vaccine is the preparation of an Outline of Production. *See* 9 C.F.R. §§ 114.8, 114.9 (1994). The Outline of Production must contain detailed highly technical data on every step in the design, manufacture, packaging and testing of all animal vaccines. *See* 9 C.F.R. § 114.9(d) (1994). The Outline of Production must be specifically approved by APHIS as a condition to product licensure. 9 C.F.R. §§ 102.5(d)(1), 114.8(a) (1994). No changes may be made in an approved Outline of

Production without prior approval from APHIS. 9 C.F.R. § 102.5(d)(1) (1994).

5. Among the mandatory prerequisites to licensure is satisfaction of an elaborate, APHIS-specified testing protocol. *See* 9 C.F.R. Part 113 (1994). APHIS requires detailed tests by which the licensee must assure the purity, safety, potency and efficacy of the product. *See, e.g.*, the Standard Procedures found at 9 C.F.R. §§ 113.25-55 (1994) for safety and purity, and the specific tests required to assure potency and efficacy of bacterial and viral animal vaccines found at 9 C.F.R. §§ 113.64-332 (1994). Where a proposed vaccine contains several different viral or bacterial fractions,[1] not only must the overall product be tested as required by APHIS, each individual fraction must be fully tested as if each were to be manufactured and distributed as a separate product. 9 C.F.R. § 113.7(a) (1994). All test and research reports must be submitted to APHIS for its review prior to licensure. 9 C.F.R. § 102.3(b)(2)(ii) (1994).

6. In addition to testing requirements, APHIS has also prescribed extensive standards for the labelling of animal vaccines. *See* 9 C.F.R. § 112 (1994). APHIS requires all animal vaccines to contain certain mandatory information on all labels, including the container label, the carton label, and any product insert, circular or leaflet. 9 C.F.R. § 112.2 (1994). The manufacture must submit all label text and design features, in final format, to APHIS prior to licensure. 9 C.F.R. § 102.3(b)(2)(iv) (1994). All proposed

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[1] A "fraction" is a specific viral or bacterial antigen which constitutes a component of an overall biological product. 9 C.F.R. § 101.3(f) (1994).

labels must be reviewed for compliance with the regulations and specifically approved in writing by APHIS, and *only* approved labels may accompany veterinary biologics sold on the marketplace. 9 C.F.R. § 112.5(c) (1994). If a manufacturer of a licensed product seeks to alter in any manner an already-approved label, APHIS must review and specifically approve the modified label before it may be used. *Id.*

7. Once all necessary pre-licensure testing required by APHIS has been completed and the product label has been specifically approved. APHIS may then issue a license for the particular vaccine. *See* 9 C.F.R. § 102.3(b) (1994). Such does *not*, however, automatically permit the vaccine to be released for sale. Before any serial, or lot, of vaccine may be sold, each serial must be tested by the manufacturer or by APHIS for purity, safety, potency and efficacy. *See* 9 C.F.R. §§ 113.3 (sampling of products), 113.5(a) (general testing), 113.6 (APHIS testing). If unsatisfactory results are obtained either by APHIS or the manufacturer, the serial may *not* be released into the market. 9 C.F.R. § 113.6(b) (1994).

8. I have personally reviewed the applications made by SBC to APHIS to obtain licenses for the animal vaccines involved in this litigation. A true and correct copy of the license issued by APHIS on January 6, 1989, under USDA License No. 1187.21 for *CattleMaster 4 is attached hereto as Exhibit A. A true and correct copy of the license issued by APHIS on December 5, 1985, bearing USDA License No. 4723.00 for Ultrabac7/Somubac is attached hereto as Exhibit B.

9. Each of the SBC vaccines involved in this litigation, through the licensure process and through post-licensure testing and evaluation, has been determined by APHIS to satisfy all requirements for purity, safety, potency, and efficacy contained in the APHIS standards. Each has been designed, manufactured and tested pursuant to APHIS standards, and of necessity APHIS approved the content and sufficiency of all design, manufacturing and testing data submitted prior to licensure of each vaccine. In addition, the text, layout, and design of all labelling on these vaccines, including the packaging and product inserts, have been specifically approved in writing by APHIS.

FURTHER AFFIANT SAITH NOT.

/s/ Cyril G. Gay
Cyril G. Gay, D.V.M., Ph.D.

Subscribed and sworn to before me
this 28th day of October, 1994.

/s/ Nancy Hock
Notary Public

GENERAL NOTARY-
State of Nebraska
NANCY HOCK
My Comm. Exp. Feb. 14, 1997

EXHIBIT A

CONFIDENTIAL

UNITED STATES
DEPARTMENT OF AGRICULTURE

UNITED STATES VETERINARY BIOLOGICAL PRODUCT LICENSE

Washington, D.C.,

January 6, 1989

This to Certify that, pursuant to the terms of the Act of Congress approved March 4, 1913 (37 Stat. 832), governing the preparation, sale, barter, exchange, shipment, and importation of viruses, serums, toxins, and analogous products intended for use in the treatment of domestic animals, the person holding United States Veterinary Biologics Establishment License No. 189 *is authorized to prepare in the facilities designated in the establishment license:*

BOVINE RHINOTRACHEITIS-VIRUS
DIARRHEA-PARAINFLUENZA$_3$-
RESPIRATORY SYNCYTIAL VIRUS VACCINE

Modified Live and Killed Virus

Code 1187.21

Preparation shall be in accordance with the provisions of the Act, the regulations made thereunder, and additional restrictions or requirements when listed below.

This license is subject to termination as provided in the regulations made under the authority contained in said Act, and to

suspension or revocation if the licensee violates or fails to comply with said Act or the regulations made thereunder.

/s/ Terry L. Medley
Animal and Plant Health
Inspection Service
Acting Director
Biotechnology, Biologics, and
Environmental Protection

EXHIBIT B

CONFIDENTIAL

UNITED STATES
DEPARTMENT OF AGRICULTURE

UNITED STATES VETERINARY BIOLOGICAL PRODUCT LICENSE

Washington, D.C.,

December 5, 1985

This to Certify that, pursuant to the terms of the Act of Congress approved March 4, 1913 (37 Stat. 832), governing the preparation, sale, barter, exchange, shipment, and importation of viruses, serums, toxins, and analogous products intended for use in the treatment of domestic animals, the person holding United States Veterinary Biologics Establishment License No. 225 is authorized to prepare in the facilities designated in the establishment license:

CLOSTRIDIUM CHAUVOEI-SEPTICUM-NOVYI-SORDELLII-PERFRINGENS

TYPES C & D-HAEMOPHILUS SOMNUS BACTERIN-TOXOID

Code 7423.00

Preparation shall be in accordance with the provisions of the Act, the regulations made thereunder, and additional restrictions or requirements when listed below.

This license is subject to termination as provided in the regulations made under the authority contained in said Act, and to suspension or revocation if the licensee violates or fails to comply with said Act or the regulations made thereunder.

SM 02023

/s/ B.J. Fichtner
Acting Deputy Adminstrator,
Veterinary Services
Animal and Plant Health
Inspection Service

LAW OFFICES

WHITNEY & POTTS, LTD.
118 WEST MAIN STREET
PO BOX 368
ELMWOOD, ILLINOIS 61529-0368

TELEPHONE 742-2591 OR 742-3611
FAX 742-8684
AREA CODE 309

ROBERT L. POTTS

MATTHEW C. POTTS
ASSOCIATE

L. RICHARD WHITNEY
(1908-1965)
GEORGE I. WHITNEY
(1938-1987)

February 1, 1995

Janell M. Gabor, Esq.
Scott A. Smith, Esq.
POPHAM, HAIK, SCHNOBRICH &
KAUFMAN, LTD.
3300 Piper Jaffray Tower
222 Ninth Street South
Minneapolis, MN 55402

Re: Lynnbrook Farms vs. Smithkline Beecham; Case No. 94-CV-1227; Stipulation for Stay of Application of Rule 26.

Dear Ms. Gabor and Mr. Smith:

Please be advised that we are in receipt of your Entry of Appearance which was recently filed with the Court, and we look forward to working with you towards the resolution of the above-captioned case.

Also, we have enclosed herewith a Stipulation For An Order to Stay the Application of Rule 26 During the Pendency of Defendant's Motion To Dismiss and Motion for Summary Judgment since it has recently come to our

attention that it is proper in the Central District of Illinois to stay the application of this Rule while Motions such as those filed herein are pending. A Stipulation such as this would be mutually beneficial to both of our firms and our clients so that time will not have to be spent on discovery until we know exactly what the results of the Motions will be.

If you have any questions in this regard, then please do not hesitate to contact our office. Otherwise, please execute the Stipulation and return the same to our office as soon as possible so that we may have it filed. Thank you for your anticipated cooperation.

Respectfully,

WHITNEY & POTTS, LTD.

/s/ Matthew C. Potts
Matthew C. Potts

MCP:jc
Enclosure
/lit/lynnbr.stp

IN THE UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF ILLINOIS
PEORIA DIVISION

LYNNBROOK FARMS, an Illinois General Partnership, Plaintiff, v. SMITHKLINE BEECHAM CORPORATION, and NORDEN LABORATORIES, INC., Defendants.	)	Case No. 94-CV-1227

STIPULATION FOR AN ORDER TO STAY THE APPLICATION OF RULE 26 DURING THE PENDENCY OF DEFENDANT'S MOTION TO DISMISS AND MOTION FOR SUMMARY JUDGMENT

(Filed Feb. 15, 1995)

NOW COME the Plaintiff, LYNNBROOK FARMS, by and through its Attorneys, WHITNEY & POTTS, LTD., and the Defendant, SMITHKLINE BEECHAM CORPORATION, by and through its Attorneys, POPHAM, HAIK, SCHNOBRICH & KAUFMAN, LTD., and they do hereby stipulate and agree in substance and in form to the entry of the following Order to stay the application of Rule 26

during the pendency of Defendant's Motion To Dismiss and Motion For Summary Judgment.

LYNNBROOK FARMS,
an Illinois General
Partnership

By: /s/ Matthew Potts
One of its
Attorneys

WHITNEY & POTTS, LTD.
Attorneys for Plaintiff
118 West Main Street
P. O. Box 368
Elmwood, IL 61529-0368
Telephone: (309) 741-2591

SMITHKLINE BEECHAM
CORPORATION,

By: /s/ Janell Gabor
One of its
Attorneys

POPHAM, HAIK,
SCHNOBRICH &
KAUFMAN, LTD.,
Attorneys for Defendant
3300 Piper Jaffray Tower
222 Ninth Street South
Minneapolis, MN 55402
Telephone: (612) 333-4800

94-1227
Lynnbrook Farms
v.
Smithline

ORDER

(Filed Feb. 15, 1995)

Pursuant to the foregoing Stipulation of the parties hereto, it is hereby Ordered that the application of Rule 26 be stayed during the pendency of Defendant's Motion To Dismiss and Motion For Summary Judgment

ENTERED this 15th day of February , 1995.

/s/ Michael M. Mihm
JUDGE

[LOGO]

United States Department of Agriculture | Animal and Plant Health Inspection Service | Washington, D.C. 20250

December 22, 1995

Honorable Paul David Wellstone
United States Senator
417 Litchfield Avenue, SW.
Willmar, Minnesota 55201

Dear Senator Wellstone:

Thank you for your letter of December 6, 1995, on behalf of your constituents Randy and Patty Brandt of Marshall, Minnesota, concerning their lawsuit against a USDA licensed manufacturer of veterinary biological products. Your letter requested a written clarification of the scope of our preemption of State law under the Virus-Serum-Toxin Act (VSTA), 21 U.S.C. 151 *et seq.*

On October 19, 1990, we published a proposed rule in the *Federal Register* (55 FR 42392). The purpose of the proposed rule was to clarify our regulations with respect to State restrictions on the use and distribution of veterinary biological products and to specify how a person could request that Federal restrictions be imposed on such products.

On August 27, 1992, we published our final rule (57 FR 38758). A copy of that rule is enclosed for your information. We stated in that rule that in order to maintain uniform national standards regarding veterinary biological products (including labeling), States are not free to

impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product. We promulgated this rule in response to regulatory actions by certain States which attempted to impose requirements concerning USDA licensed veterinary biological products which were different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product.

Our intent in promulgating the rule was, and continues to be, to preempt states from imposing requirements either through statutes, regulations, or other means that are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product. Such requirements would include, but are not limited to production, testing, distribution, or labeling requirements. We did not intend to preempt common law actions for damages arising from noncompliance with USDA regulatory standards.

Sincerely,

/s/ Terry L. Medley
Terry L. Medley
Acting Administrator

Enclosure

UNITED STATES COURT OF APPEALS *jc*

For the Seventh Circuit
Chicago, Illinois 60604

August 5, 1996

Before

Hon. JOEL M. FLAUM, *Circuit Judge*

LYNNBROOK FARMS, an Illinois General Partnership, Plaintiff-Appellant,	] Appeal from the United States District Court for the Central District of Illinois, Peoria Division.
No. 95-2051 v.	] No. 94 C 1227
SMITHKLINE BEECHAM CORPORATION, Defendant-Appellee.	] Michael M. Mihm, Chief Judge.

Upon consideration of:

1. **MOTION TO RECALL MANDATE** filed July 10, 1996, by counsel for the appellant;

2. **APPELLEE'S MEMORANDUM OF LAW IN OPPOSITION TO APPELLANT'S MOTION TO RECALL MANDATE** filed July 22, 1996, by counsel; and

3. July 25, 1996 letter to the clerk from counsel for the appellee;

We have jurisdiction to consider the motion to recall the mandate, which is **DENIED.**

United States Constitution, Article VI, cl. 2

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties, made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

21 U.S.C. § 151. Preparation and sale of worthless or harmful products for domestic animals prohibited; preparation to be in compliance with rules at licensed establishments

It shall be unlawful for any person, firm, or corporation to prepare, sell, barter, or exchange in the District of Columbia, or in the Territories, or in any place under the jurisdiction of the United States, or to ship or deliver for shipment in or from the United States, the District of Columbia, any territory of the United States, or any place under the jurisdiction of the United States, any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals, and no person, firm, or corporation shall prepare, sell, barter, exchange, or ship as aforesaid any virus, serum, toxin, or analogous product manufactured within the United States and intended for use in the treatment of domestic animals, unless and until the said virus, serum, toxin, or analogous product shall have been prepared, under and in compliance with regulations prescribed by the Secretary of Agriculture, at an establishment holding an unsuspended and unrevoked license issued by the Secretary of Agriculture as hereinafter authorized.

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§ 152. Importation regulated and prohibited.

The importation into the United States of any virus, serum, toxin, or analogous product for use in the treatment of domestic animals, and the importation of any

worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, is prohibited without (1) a permit from the Secretary of Agriculture, or (2) in the case of an article originating in Canada, such permit or, in lieu of such permit, such certification by Canada as may be prescribed by the Secretary of Agriculture.

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§ 153. Inspection of imports; denial of entry and destruction

The Secretary of Agriculture is hereby authorized to cause the Bureau of Animal Industry to examine and inspect all viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, which are being imported or offered for importation into the United States, to determine whether such viruses, serums, toxins, and analogous products are worthless, contaminated, dangerous, or harmful, and if it shall appear that any such virus, serum, toxin, or analogous product for use in the treatment of domestic animals, is worthless, contaminated, dangerous, or harmful, the same shall be denied entry and shall be destroyed or returned at the expense of the owner or importer.

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§ 154. Regulations for preparation and sale; licenses

The Secretary of Agriculture is hereby authorized to make and promulgate from time to time such rules and

regulations as may be necessary to prevent the preparation, sale, barter, exchange, or shipment as aforesaid of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals or otherwise to carry out this paragraph, and to issue, suspend, and revoke licenses for the maintenance of establishments for the preparation of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals intended for sale, barter, exchange, or shipment as aforesaid.

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§ 154a. Special licenses for special circumstances; expedited procedure; conditions; exemptions; criteria

In order to meet an emergency condition, limited market or local situation, or other special circumstance (including production solely for intrastate use under a State-operated program), the Secretary may issue a special license under an expedited procedure on such conditions as are necessary to assure purity, safety, and a reasonable expectation of efficacy. The Secretary shall exempt by regulation from the requirement of preparation pursuant to an unsuspended and unrevoked license any virus, serum, toxin, or analogous product prepared by any person, firm, or corporation –

(1) solely for administration to animals of such person, firm, or corporation;

(2) solely for administration to animals under a veterinarian-client-patient-relationship in the course of the State licensed professional practice of veterinary medicine by such person, firm, or corporation; or

(3) solely for distribution within the State of production pursuant to a license granted by such State under a program determined by the Secretary to meet criteria under which the State –

(A) may license virus, serum, toxin, and analogous products and establishments that produce such products;

(B) may review the purity, safety, potency, and efficacy of such products prior to licensure;

(C) may review product test results to assure compliance with applicable standards for purity, safety, and potency, prior to release to the market;

(D) may deal effectively with violations of State law regulating virus, serum, toxin, and analogous products; and

(E) exercises the authority referred to in subclauses (A) through (D) consistent with the intent of this paragraph of prohibiting the preparation, sale, barter, exchange, or shipment of worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous products.

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§ 155. Permits for importation

The Secretary of Agriculture is hereby authorized to issue permits for the importation into the United States of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, which are not worthless, contaminated, dangerous, or harmful.

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§ 156. Licenses conditioned on permitting inspection; suspension of licenses

All licenses issued under authority of this chapter to establishments where such viruses, serums, toxins, or analogous products are prepared for sale, barter, exchange, or shipment as aforesaid, shall be issued on condition that the licensee shall permit the inspection of such establishments and of such products and their preparation; and the Secretary of Agriculture may suspend or revoke any permit or license issued under authority of said chapter, after opportunity for hearing has been granted the licensee or importer, when the Secretary of Agriculture is satisfied that such license or permit is being used to facilitate or effect the preparation, sale, barter, exchange, or shipment as aforesaid, or the importation into the United States of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals.

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§ 157. Same; inspection daytime or nighttime

Any officer, agent, or employee of the Department of Agriculture duly authorized by the Secretary of Agriculture for the purpose may, at any hour during the daytime or nighttime, enter and inspect any establishment where any virus, serum, toxin, or analogous product for use in the treatment of domestic animals is prepared for sale, barter, exchange, or shipment as aforesaid.

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§ 158. Offenses; punishment

Any person, firm, or corporation who shall violate any of the provisions of this chapter shall be deemed guilty of a misdemeanor, and shall, upon conviction, be punished by a fine of not exceeding $1,000 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

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§ 159. Enforcement penalties applicable; Congressional findings

The procedures of sections 672, 673, and 674 of this title (relating to detentions, seizures and condemnations, and injunctions, respectively) shall apply to the enforcement of this chapter with respect to any product prepared, sold, bartered, exchanged, or shipped in violation of this chapter or a regulation promulgated under this

chapter. The provisions (including penalties) of section 675 of this title shall apply to the performance of official duties under this chapter. Congress finds that (i) the products and activities that are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce or the free flow thereof, and (ii) regulation of the products and activities as provided in this chapter is necessary to prevent and eliminate burdens on such commerce and to effectively regulate such commerce.